

Dexafree® 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor, pharmacist or nurse.
- * This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- * If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

Your medicine is called Dexafree 1 mg/ml, eye drops, solution in single-dose container, but will be referred to as Dexafree throughout the leaflet.

What is in this leaflet:

- 1 What Dexafree is and what it is used for
- 2 What you need to know before you use Dexafree
- 3 How to use Dexafree
- 4 Possible side effects
- 5 How to store Dexafree
- 6 Contents of the pack and other information

1 What Dexafree is and what it is used for

Dexafree contains dexamethasone, which is a corticosteroid used to stop inflammatory symptoms (such as pain, heat swelling and redness).

Dexafree is used to treat inflammation of your eyes.

If you have an infected eye (red eye, tears and mucous), you will be given another medicine to take at the same time as Dexafree. See Section 2.

2 What you need to know before you use Dexafree

Do not use Dexafree

- * if you are suffering from an eye infection that you are not using a medicine for,
- * if you have damage on the surface of the eye (small holes, ulcers or injury which have not healed properly),
- * if you have high pressure in the eye known to be caused by glucosteroids (family of corticosteroid medicines),
- * if you are allergic (hypersensitive) to dexamethasone sodium phosphate, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tell your doctor, pharmacist or nurse before using Dexafree.

DO NOT INJECT, DO NOT SWALLOW.

Avoid contact between the dispenser tip and the eye or eyelids.

- * close monitoring of the eye is needed during the use of Dexafree and in particular:
 - for children and the elderly. More frequent monitoring is advised,
 - if you have an eye infection. Only use Dexafree if you are using an anti-infective medicine,
 - if you have a corneal ulcer, an open sore on the surface of the eye with sometimes extreme pain, tears, squinting and loss of vision. Do not use Dexafree, unless inflammation is the main cause of delayed healing,
 - if you suffer from high pressure in the eye. If you have already had high pressure in the eye after using an eye steroid medicine, you are at risk of having this again if you use Dexafree,
 - if you have glaucoma, a condition which can cause damage to the optic nerve and may cause loss of sight.
- * children: do not use for long-term treatment without a break.
- * if you have severe allergic conjunctivitis (redness, swelling, itching and tears in the eye) that another medicine has not been able to treat, only use Dexafree for a short period of time.
- * diabetic: if you are diabetic, tell your ophthalmologist or optician.
- * if you have a red eye that has not been diagnosed, do not use Dexafree.
- * contact lenses: do not wear contact lenses when you are using Dexafree.

Talk to your doctor if you notice swelling and weight gain around your middle and in your face as these are usually the first signs of a condition called Cushing's syndrome. Decrease in the function of the adrenal gland may develop after stopping a long-term or intensive treatment with Dexafree. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Tell your doctor if you have blurred vision or other visual disturbances.

Other medicines and Dexafree

If you are using any other eye medicine, wait 15 minutes between using each medicine.

Tell your doctor if you are using ritonavir or cobicistat, as these medicines may increase the amount of dexamethasone in the blood. Using eye drops containing steroids and eye drops containing beta-blockers (to treat high pressure in the eye) together may cause settling of calcium phosphate on the surface of the eye.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

There is not enough information on the use of Dexafree during pregnancy to know the possible side effects.

For this reason, the use of Dexafree during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Dexafree is low. Dexafree can be used when breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

You may have blurred vision for a short time after using your drops. Wait until your vision is normal before you drive or use machines.

Dexafree contains phosphates

This medicine contains 80 micrograms phosphates in each drop.

3 How to use Dexafree

Dose

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 drop, 4 to 6 times a day in the eye to be treated. If your condition is more serious, you may be told to start with 1 drop every hour and then change to 1 drop every 4 hours, after the medicine has started to work.

It is important to lower the dose slowly to stop the condition getting worse again.

- In elderly people: there is no need to adjust the dose.
- In children: do not use for long-term treatment without a break.

Method of administration

Ocular use: this medicine is eye drops to be used in the eye.

- 1 Wash your hands well before using these drops.
- 2 Look upwards and pull the lower eyelid down with your finger. Put one drop into the eye to be treated.
- 3 Immediately after you have put the eye drop in, press lightly with your finger on the inside corner of your eye, nearest your nose for few minutes. This helps to stop the eye drops spreading into the rest of your body.
- 4 Throw away the single-dose container after use. Do not keep it to use again.

Frequency of use

4 to 6 times a day.

Duration of treatment

You will usually need to use your drops for a few days and no longer than 14 days.

Dexafree® 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Patient Information Leaflet (continued)

If you use more Dexafree than you should

Rinse the eye with sterile water if you have put too much medicine in your eye and your eye feels sore.

Immediately tell your doctor or pharmacist.

If you forget to use Dexafree

Do not use a double dose to make up for a forgotten dose.

If you stop using Dexafree

Do not stop using this medicine suddenly.

Always tell your doctor if you are thinking about stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Endocrine conditions:

Not known: frequency cannot be estimated from the available data

- * Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

Eye conditions:

Very common (may affect more than 1 in 10 people):

- * high pressure in the eye after 2 weeks of using the drops.

Common (may affect up to 1 in 10 people):

- * discomfort, irritation, burning, stinging, itching and blurred vision after use. These are usually mild and do not last long.

Uncommon (may affect up to 1 in 100 people):

- * signs of an allergic reaction,
- * healing which takes longer than expected,
- * cloudy lens (cataract),
- * infections,
- * high pressure in the eye (glaucoma).

Very rare (may affect up to 1 in 10,000 people):

- * inflamed surface of the eye giving red eye, tears and irritation (conjunctivitis),
- * wide pupil (mydriasis),
- * swelling of the face (facial oedema),
- * drooping eyelids (ptosis),
- * inflammation of the eye which causes pain and redness (uveitis),
- * settling of calcium on the surface of the eye (calcification of the cornea),
- * inflamed surface of the eye giving blurred vision, dry eyes, sensitivity to light, burning, tears and a sandy sensation in your eye (crystalline keratopathy),
- * changes in the thickness of the surface of the eye,
- * swelling of the surface of the eye (corneal oedema),
- * ulcer on the surface of the eye causing pain, tears, squinting and vision loss,
- * small holes on the surface of the eye (perforation of the cornea).

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Dexafree

- * **Keep out of the sight and reach of children.**
- * Keep the single-dose containers in the sachet, in order to protect from light.
- * After first opening of the sachet: use the single-dose containers within 15 days.
- * After opening of the single-dose container: use immediately and then throw away the single-dose container after use.
- * Do not use Dexafree after the expiry date which is stated on the pouch label or carton. The expiry date refers to the last day of the month.
- * If your doctor tells you to stop taking this medicine, return any unused solution to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
- * If the solution becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Dexafree contains:

Each 1 ml of solution contains 1 mg of dexamethasone phosphate as dexamethasone sodium phosphate.

Also contains disodium edetate, disodium phosphate dodecahydrate, sodium chloride, water for injections.

What Dexafree looks like and contents of the pack

Dexafree is a clear, colourless to slightly brown solution.

Each pack contains 20 x 0.4ml and 30 x 0.4ml single-dose containers.

Manufacturer and Licence Holder

Manufactured by Laboratoire Unither, 1 Rue de L'Arquerie, 50200 Coutances, France and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

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Dexafree 1 mg/ml, eye drops,
solution in single-dose
container

Dexafree is a registered trademark of Laboratoires Thea.

Revision date: 19/11/25

**Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet
in a format suitable for you**

Dexafree® 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

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Your medicine is called Dexafree 1 mg/ml, eye drops, solution in single-dose container, but will be referred to as Dexafree throughout the leaflet.

What is in this leaflet:

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- 6 Contents of the pack and other information

1 What Dexafree is and what it is used for

Dexafree contains dexamethasone, which is a corticosteroid used to stop inflammatory symptoms (such as pain, heat swelling and redness).

Dexafree is used to treat inflammation of your eyes.

If you have an infected eye (red eye, tears and mucous), you will be given another medicine to take at the same time as Dexafree. See Section 2.

2 What you need to know before you use Dexafree

Do not use Dexafree

- * if you are suffering from an eye infection that you are not using a medicine for,
- * if you have damage on the surface of the eye (small holes, ulcers or injury which have not healed properly),
- * if you have high pressure in the eye known to be caused by glucosteroids (family of corticosteroid medicines),
- * if you are allergic (hypersensitive) to dexamethasone sodium phosphate, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tell your doctor, pharmacist or nurse before using Dexafree.

DO NOT INJECT, DO NOT SWALLOW.

Avoid contact between the dispenser tip and the eye or eyelids.

- * close monitoring of the eye is needed during the use of Dexafree and in particular:
 - for children and the elderly. More frequent monitoring is advised,
 - if you have an eye infection. Only use Dexafree if you are using an anti-infective medicine,
 - if you have a corneal ulcer, an open sore on the surface of the eye with sometimes extreme pain, tears, squinting and loss of vision. Do not use Dexafree, unless inflammation is the main cause of delayed healing,
 - if you suffer from high pressure in the eye. If you have already had high pressure in the eye after using an eye steroid medicine, you are at risk of having this again if you use Dexafree,
 - if you have glaucoma, a condition which can cause damage to the optic nerve and may cause loss of sight.
- * children: do not use for long-term treatment without a break.
- * if you have severe allergic conjunctivitis (redness, swelling, itching and tears in the eye) that another medicine has not been able to treat, only use Dexafree for a short period of time.
- * diabetic: if you are diabetic, tell your ophthalmologist or optician.
- * if you have a red eye that has not been diagnosed, do not use Dexafree.
- * contact lenses: do not wear contact lenses when you are using Dexafree.

Talk to your doctor if you notice swelling and weight gain around your middle and in your face as these are usually the first signs of a condition called Cushing's syndrome. Decrease in the function of the adrenal gland may develop after stopping a long-term or intensive treatment with Dexafree. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Tell your doctor if you have blurred vision or other visual disturbances.

Other medicines and Dexafree

If you are using any other eye medicine, wait 15 minutes between using each medicine.

Tell your doctor if you are using ritonavir or cobicistat, as these medicines may increase the amount of dexamethasone in the blood. Using eye drops containing steroids and eye drops containing beta-blockers (to treat high pressure in the eye) together may cause settling of calcium phosphate on the surface of the eye.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

There is not enough information on the use of Dexafree during pregnancy to know the possible side effects.

For this reason, the use of Dexafree during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Dexafree is low. Dexafree can be used when breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

You may have blurred vision for a short time after using your drops. Wait until your vision is normal before you drive or use machines.

Dexafree contains phosphates

This medicine contains 80 micrograms phosphates in each drop.

3 How to use Dexafree

Dose

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 drop, 4 to 6 times a day in the eye to be treated. If your condition is more serious, you may be told to start with 1 drop every hour and then change to 1 drop every 4 hours, after the medicine has started to work.

It is important to lower the dose slowly to stop the condition getting worse again.

- In elderly people: there is no need to adjust the dose.
- In children: do not use for long-term treatment without a break.

Method of administration

Ocular use: this medicine is eye drops to be used in the eye.

- 1 Wash your hands well before using these drops.
- 2 Look upwards and pull the lower eyelid down with your finger. Put one drop into the eye to be treated.
- 3 Immediately after you have put the eye drop in, press lightly with your finger on the inside corner of your eye, nearest your nose for few minutes. This helps to stop the eye drops spreading into the rest of your body.
- 4 Throw away the single-dose container after use. Do not keep it to use again.

Frequency of use

4 to 6 times a day.

Duration of treatment

You will usually need to use your drops for a few days and no longer than 14 days.

Dexafree® 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Patient Information Leaflet (continued)

If you use more Dexafree than you should

Rinse the eye with sterile water if you have put too much medicine in your eye and your eye feels sore.

Immediately tell your doctor or pharmacist.

If you forget to use Dexafree

Do not use a double dose to make up for a forgotten dose.

If you stop using Dexafree

Do not stop using this medicine suddenly.

Always tell your doctor if you are thinking about stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Endocrine conditions:

Not known: frequency cannot be estimated from the available data

- * Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

Eye conditions:

Very common (may affect more than 1 in 10 people):

- * high pressure in the eye after 2 weeks of using the drops.

Common (may affect up to 1 in 10 people):

- * discomfort, irritation, burning, stinging, itching and blurred vision after use. These are usually mild and do not last long.

Uncommon (may affect up to 1 in 100 people):

- * signs of an allergic reaction,
- * healing which takes longer than expected,
- * cloudy lens (cataract),
- * infections,
- * high pressure in the eye (glaucoma).

Very rare (may affect up to 1 in 10,000 people):

- * inflamed surface of the eye giving red eye, tears and irritation (conjunctivitis),
- * wide pupil (mydriasis),
- * swelling of the face (facial oedema),
- * drooping eyelids (ptosis),
- * inflammation of the eye which causes pain and redness (uveitis),
- * settling of calcium on the surface of the eye (calcification of the cornea),
- * inflamed surface of the eye giving blurred vision, dry eyes, sensitivity to light, burning, tears and a sandy sensation in your eye (crystalline keratopathy),
- * changes in the thickness of the surface of the eye,
- * swelling of the surface of the eye (corneal oedema),
- * ulcer on the surface of the eye causing pain, tears, squinting and vision loss,
- * small holes on the surface of the eye (perforation of the cornea).

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Dexafree

- * **Keep out of the sight and reach of children.**
- * Keep the single-dose containers in the sachet, in order to protect from light.
- * After first opening of the sachet: use the single-dose containers within 15 days.
- * After opening of the single-dose container: use immediately and then throw away the single-dose container after use.
- * Do not use Dexafree after the expiry date which is stated on the pouch label or carton. The expiry date refers to the last day of the month.
- * If your doctor tells you to stop taking this medicine, return any unused solution to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
- * If the solution becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Dexafree contains:

Each 1 ml of solution contains 1 mg of dexamethasone phosphate as dexamethasone sodium phosphate.

Also contains disodium edetate, disodium phosphate dodecahydrate, sodium chloride, water for injections.

What Dexafree looks like and contents of the pack

Dexafree is a clear, colourless to slightly brown solution.

Each pack contains 20 x 0.4ml and 30 x 0.4ml single-dose containers.

Manufacturer and Licence Holder

Manufactured by Excelvision, Rue De La Lombardiere, 07100 Annonay, France and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

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Dexafree 1 mg/ml, eye drops,
solution in single-dose
container

Dexafree is a registered trademark of Laboratoires Thea.

Revision date: 19/11/25

**Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet
in a format suitable for you**

Dexamethasone Phosphate 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

Your medicine is called Dexamethasone Phosphate 1 mg/ml, eye drops, solution in single-dose container, but will be referred to as Dexamethasone Phosphate throughout the leaflet.

What is in this leaflet:

- 1 What Dexamethasone Phosphate is and what it is used for
- 2 What you need to know before you use Dexamethasone Phosphate
- 3 How to use Dexamethasone Phosphate
- 4 Possible side effects
- 5 How to store Dexamethasone Phosphate
- 6 Contents of the pack and other information

1 What Dexamethasone Phosphate is and what it is used for

Dexamethasone Phosphate contains dexamethasone, which is a corticosteroid used to stop inflammatory symptoms (such as pain, heat swelling and redness).

Dexamethasone Phosphate is used to treat inflammation of your eyes.

If you have an infected eye (red eye, tears and mucous), you will be given another medicine to take at the same time as Dexamethasone Phosphate. See Section 2.

2 What you need to know before you use Dexamethasone Phosphate

Do not use Dexamethasone Phosphate

- * if you are suffering from an eye infection that you are not using a medicine for,
- * if you have damage on the surface of the eye (small holes, ulcers or injury which have not healed properly),
- * if you have high pressure in the eye known to be caused by glucosteroids (family of corticosteroid medicines),
- * if you are allergic (hypersensitive) to dexamethasone sodium phosphate, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tell your doctor, pharmacist or nurse before using Dexamethasone Phosphate.

DO NOT INJECT, DO NOT SWALLOW.

Avoid contact between the dispenser tip and the eye or eyelids.

- * close monitoring of the eye is needed during the use of Dexamethasone Phosphate and in particular:
 - for children and the elderly. More frequent monitoring is advised,
 - if you have an eye infection. Only use Dexamethasone Phosphate if you are using an anti-infective medicine,
 - if you have a corneal ulcer, an open sore on the surface of the eye with sometimes extreme pain, tears, squinting and loss of vision. Do not use Dexamethasone Phosphate, unless inflammation is the main cause of delayed healing,
 - if you suffer from high pressure in the eye.
- If you have already had high pressure in the eye after using an eye steroid medicine, you are at risk of having this again if you use Dexamethasone Phosphate,
- if you have glaucoma, a condition which can cause damage to the optic nerve and may cause loss of sight.

- * children: do not use for long-term treatment without a break.
- * if you have severe allergic conjunctivitis (redness, swelling, itching and tears in the eye) that another medicine has not been able to treat, only use Dexamethasone Phosphate for a short period of time.
- * diabetic: if you are diabetic, tell your ophthalmologist or optician.
- * if you have a red eye that has not been diagnosed, do not use Dexamethasone Phosphate.
- * contact lenses: do not wear contact lenses when you are using Dexamethasone Phosphate.

Talk to your doctor if you notice swelling and weight gain around your middle and in your face as these are usually the first signs of a condition called Cushing's syndrome. Decrease in the function of the adrenal gland may develop after stopping a long-term or intensive treatment with Dexamethasone Phosphate. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Tell your doctor if you have blurred vision or other visual disturbances.

Other medicines and Dexamethasone Phosphate

If you are using any other eye medicine, wait 15 minutes between using each medicine. Tell your doctor if you are using ritonavir or cobicistat, as these medicines may increase the amount of dexamethasone in the blood. Using eye drops containing steroids and eye drops containing beta-blockers (to treat high pressure in the eye) together may cause settling of calcium phosphate on the surface of the eye.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

There is not enough information on the use of Dexamethasone Phosphate during pregnancy to know the possible side effects.

For this reason, the use of Dexamethasone Phosphate during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Dexamethasone Phosphate is low. Dexamethasone Phosphate can be used when breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

You may have blurred vision for a short time after using your drops. Wait until your vision is normal before you drive or use machines.

Dexamethasone Phosphate contains phosphates

This medicine contains 80 micrograms phosphates in each drop.

3 How to use Dexamethasone Phosphate

Dose

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is 1 drop, 4 to 6 times a day in the eye to be treated. If your condition is more serious, you may be told to start with 1 drop every hour and then change to 1 drop every 4 hours, after the medicine has started to work.

It is important to lower the dose slowly to stop the condition getting worse again.

- In elderly people: there is no need to adjust the dose.
- In children: do not use for long-term treatment without a break.

Method of administration

Ocular use: this medicine is eye drops to be used in the eye.

1. Wash your hands well before using these drops.
2. Look upwards and pull the lower eyelid down with your finger. Put one drop into the eye to be treated.
3. Immediately after you have put the eye drop in, press lightly with your finger on the inside corner of your eye, nearest your nose for few minutes. This helps to stop the eye drops spreading into the rest of your body.
4. Throw away the single-dose container after use. Do not keep it to use again.

Dexamethasone Phosphate 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Patient Information Leaflet (continued)

Frequency of use

4 to 6 times a day.

Duration of treatment

You will usually need to use your drops for a few days and no longer than 14 days.

If you use more Dexamethasone Phosphate than you should

Rinse the eye with sterile water if you have put too much medicine in your eye and your eye feels sore.

Immediately tell your doctor or pharmacist.

If you forget to use Dexamethasone Phosphate

Do not use a double dose to make up for a forgotten dose.

If you stop using Dexamethasone Phosphate

Do not stop using this medicine suddenly.

Always tell your doctor if you are thinking about stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Endocrine conditions:

Not known: frequency cannot be estimated from the available data

- * Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

Eye conditions:

Very common (may affect more than 1 in 10 people):

- * high pressure in the eye after 2 weeks of using the drops.

Common (may affect up to 1 in 10 people):

- * discomfort, irritation, burning, stinging, itching and blurred vision after use. These are usually mild and do not last long.

Uncommon (may affect up to 1 in 100 people):

- * signs of an allergic reaction,
- * healing which takes longer than expected,
- * cloudy lens (cataract),
- * infections,
- * high pressure in the eye (glaucoma).

Very rare (may affect up to 1 in 10,000 people):

- * inflamed surface of the eye giving red eye, tears and irritation (conjunctivitis),
- * wide pupil (mydriasis),
- * swelling of the face (facial oedema),
- * drooping eyelids (ptosis),
- * inflammation of the eye which causes pain and redness (uveitis),
- * settling of calcium on the surface of the eye (calcification of the cornea),
- * inflamed surface of the eye giving blurred vision, dry eyes, sensitivity to light, burning, tears and a sandy sensation in your eye (crystalline keratopathy),
- * changes in the thickness of the surface of the eye,
- * swelling of the surface of the eye (corneal oedema),
- * ulcer on the surface of the eye causing pain, tears, squinting and vision loss,
- * small holes on the surface of the eye (perforation of the cornea).

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Dexamethasone Phosphate

- * **Keep out of the sight and reach of children.**
- * Keep the single-dose containers in the sachet, in order to protect from light.
- * After first opening of the sachet: use the single-dose containers within 15 days.
- * After opening of the single-dose container: use immediately and then throw away the single-dose container after use.
- * Do not use Dexamethasone Phosphate after the expiry date which is stated on the pouch label or carton. The expiry date refers to the last day of the month.
- * If your doctor tells you to stop taking this medicine, return any unused solution to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
- * If the solution becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Dexamethasone Phosphate contains:

Each 1 ml of solution contains 1 mg of dexamethasone phosphate as dexamethasone sodium phosphate.

Also contains disodium edetate, disodium phosphate dodecahydrate, sodium chloride, water for injections.

What Dexamethasone Phosphate looks like and contents of the pack

Dexamethasone Phosphate is a clear, colourless to slightly brown solution. Each pack contains 20 x 0.4ml single-dose containers.

Manufacturer and Licence Holder

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If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

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PL 15184/1738

Dexamethasone Phosphate
1 mg/ml, eye drops,
solution in single-dose
container

Revision date: 19/11/25

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Dexamethasone Phosphate 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

Your medicine is called Dexamethasone Phosphate 1 mg/ml, eye drops, solution in single-dose container, but will be referred to as Dexamethasone Phosphate throughout the leaflet.

What is in this leaflet:

- 1 What Dexamethasone Phosphate is and what it is used for
- 2 What you need to know before you use Dexamethasone Phosphate
- 3 How to use Dexamethasone Phosphate
- 4 Possible side effects
- 5 How to store Dexamethasone Phosphate
- 6 Contents of the pack and other information

1 What Dexamethasone Phosphate is and what it is used for

Dexamethasone Phosphate contains dexamethasone, which is a corticosteroid used to stop inflammatory symptoms (such as pain, heat swelling and redness).

Dexamethasone Phosphate is used to treat inflammation of your eyes.

If you have an infected eye (red eye, tears and mucous), you will be given another medicine to take at the same time as Dexamethasone Phosphate. See Section 2.

2 What you need to know before you use Dexamethasone Phosphate

Do not use Dexamethasone Phosphate

- * if you are suffering from an eye infection that you are not using a medicine for,
- * if you have damage on the surface of the eye (small holes, ulcers or injury which have not healed properly),
- * if you have high pressure in the eye known to be caused by glucosteroids (family of corticosteroid medicines),
- * if you are allergic (hypersensitive) to dexamethasone sodium phosphate, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Tell your doctor, pharmacist or nurse before using Dexamethasone Phosphate.

DO NOT INJECT, DO NOT SWALLOW.

Avoid contact between the dispenser tip and the eye or eyelids.

- * close monitoring of the eye is needed during the use of Dexamethasone Phosphate and in particular:
 - for children and the elderly. More frequent monitoring is advised,
 - if you have an eye infection. Only use Dexamethasone Phosphate if you are using an anti-infective medicine,
 - if you have a corneal ulcer, an open sore on the surface of the eye with sometimes extreme pain, tears, squinting and loss of vision. Do not use Dexamethasone Phosphate, unless inflammation is the main cause of delayed healing,
 - if you suffer from high pressure in the eye.
- If you have already had high pressure in the eye after using an eye steroid medicine, you are at risk of having this again if you use Dexamethasone Phosphate,
- if you have glaucoma, a condition which can cause damage to the optic nerve and may cause loss of sight.

- * children: do not use for long-term treatment without a break.
- * if you have severe allergic conjunctivitis (redness, swelling, itching and tears in the eye) that another medicine has not been able to treat, only use Dexamethasone Phosphate for a short period of time.
- * diabetic: if you are diabetic, tell your ophthalmologist or optician.
- * if you have a red eye that has not been diagnosed, do not use Dexamethasone Phosphate.
- * contact lenses: do not wear contact lenses when you are using Dexamethasone Phosphate.

Talk to your doctor if you notice swelling and weight gain around your middle and in your face as these are usually the first signs of a condition called Cushing's syndrome. Decrease in the function of the adrenal gland may develop after stopping a long-term or intensive treatment with Dexamethasone Phosphate. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Tell your doctor if you have blurred vision or other visual disturbances.

Other medicines and Dexamethasone Phosphate

If you are using any other eye medicine, wait 15 minutes between using each medicine. Tell your doctor if you are using ritonavir or cobicistat, as these medicines may increase the amount of dexamethasone in the blood. Using eye drops containing steroids and eye drops containing beta-blockers (to treat high pressure in the eye) together may cause settling of calcium phosphate on the surface of the eye.

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy and breast-feeding

There is not enough information on the use of Dexamethasone Phosphate during pregnancy to know the possible side effects.

For this reason, the use of Dexamethasone Phosphate during pregnancy is not recommended.

It is not known if this medicine is present in breast milk. However, the dose of Dexamethasone Phosphate is low. Dexamethasone Phosphate can be used when breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

You may have blurred vision for a short time after using your drops. Wait until your vision is normal before you drive or use machines.

Dexamethasone Phosphate contains phosphates

This medicine contains 80 micrograms phosphates in each drop.

3 How to use Dexamethasone Phosphate

Dose

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is 1 drop, 4 to 6 times a day in the eye to be treated. If your condition is more serious, you may be told to start with 1 drop every hour and then change to 1 drop every 4 hours, after the medicine has started to work.

It is important to lower the dose slowly to stop the condition getting worse again.

- In elderly people: there is no need to adjust the dose.
- In children: do not use for long-term treatment without a break.

Method of administration

Ocular use: this medicine is eye drops to be used in the eye.

1. Wash your hands well before using these drops.
2. Look upwards and pull the lower eyelid down with your finger. Put one drop into the eye to be treated.
3. Immediately after you have put the eye drop in, press lightly with your finger on the inside corner of your eye, nearest your nose for few minutes. This helps to stop the eye drops spreading into the rest of your body.
4. Throw away the single-dose container after use. Do not keep it to use again.

Dexamethasone Phosphate 1 mg/ml, eye drops, solution in single-dose container

(dexamethasone sodium phosphate)

Patient Information Leaflet (continued)

Frequency of use

4 to 6 times a day.

Duration of treatment

You will usually need to use your drops for a few days and no longer than 14 days.

If you use more Dexamethasone Phosphate than you should

Rinse the eye with sterile water if you have put too much medicine in your eye and your eye feels sore.

Immediately tell your doctor or pharmacist.

If you forget to use Dexamethasone Phosphate

Do not use a double dose to make up for a forgotten dose.

If you stop using Dexamethasone Phosphate

Do not stop using this medicine suddenly.

Always tell your doctor if you are thinking about stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Endocrine conditions:

Not known: frequency cannot be estimated from the available data

- * Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").

Eye conditions:

Very common (may affect more than 1 in 10 people):

- * high pressure in the eye after 2 weeks of using the drops.

Common (may affect up to 1 in 10 people):

- * discomfort, irritation, burning, stinging, itching and blurred vision after use. These are usually mild and do not last long.

Uncommon (may affect up to 1 in 100 people):

- * signs of an allergic reaction,
- * healing which takes longer than expected,
- * cloudy lens (cataract),
- * infections,
- * high pressure in the eye (glaucoma).

Very rare (may affect up to 1 in 10,000 people):

- * inflamed surface of the eye giving red eye, tears and irritation (conjunctivitis),
- * wide pupil (mydriasis),
- * swelling of the face (facial oedema),
- * drooping eyelids (ptosis),
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