PACKAGE LEAFLET: INFORMATION FOR THE USER

Aldara™ 5% Cream
(imiquimod)

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, please ask your doctor or your pharmacist.
- 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 any get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Aldara 5% Cream but it will be referred to as Aldara cream throughout the remainder of this leaflet.

What is in this leaflet

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

1. WHAT ALDARA CREAM IS AND WHAT IT IS USED FOR

Aldara cream may be used for three different conditions. Your doctor may prescribe Aldara cream for the treatment of:

- Warts (condylomata acuminata) on the surface of the genitals (sexual organs) and around the anus (back passage)
- Superficial basal cell carcinoma.
- This is a common slow-growing form of skin cancer with a very small likelihood of spread to other parts of the body. It usually occurs in middle-aged and elderly people, especially those who are fair-skinned and is caused by too much sun exposure. If left untreated, basal cell carcinoma can disfigure, especially on the face – therefore early recognition and treatment are important.
- Actinic keratosis
  Actinic keratoses are rough areas of skin found in people who have been exposed to a lot of sunshine over the course of their lifetime. Some are skin coloured, others are greyish, pink, red or brown. They can be flat and scaly, or raised, rough, hard and warty. Aldara should only be used for flat actinic keratoses on the face and scalp in patients with a healthy immune system where your doctor has decided that Aldara is the most appropriate treatment for you.

Aldara cream helps your body´s own immune system to produce natural substances which help fight your basal cell carcinoma, actinic keratosis or the virus that has caused your warts.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ALDARA CREAM

Do not use Aldara cream
- if you are allergic to imiquimod or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Aldara cream
- If you have previously used Aldara cream or other similar preparations tell your doctor before starting this treatment.
- If you suffer from autoimmune disorders
- If you have had an organ transplant
- Do not use Aldara cream until the area to be treated has healed after previous drug or surgical treatment.
- Avoid contact with the eyes, lips and nostrils. In the event of accidental contact, remove cream by rinsing with water.
- Do not apply the cream internally.
- Do not use more cream than your doctor has advised.
- Do not cover the treated area with bandages or other dressings after you have applied Aldara cream.
- If the treated site becomes too uncomfortable, wash the cream off with mild soap and water.
  As soon as the problem has stopped you may restart to apply the cream.
- Tell your doctor if you have an abnormal blood count.

Because of the way Aldara works, there is a possibility that the cream may worsen existing inflammation in the treatment area.
- If you are being treated for genital warts follow these additional precautions:
  Men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If not washed daily the foreskin may be more likely to show signs of tightness, swelling and wearing away of the skin and result in difficulty in pulling it back. If these symptoms occur, stop the treatment immediately and call your doctor.
  If you have open sores: do not start using Aldara cream until after the sores have healed.
  If you have internal warts: do not use Aldara cream in the urethra (the hole from which urine is passed), the vagina (birth canal), the cervix (internal female organ), or anywhere inside your anus (rectum).
  Do not use this medication for more than one course if you have problems with your immune system, either due to illness or because of the medicines you are already taking. If you think this applies to you talk to your doctor.
  If you are HIV positive you should inform your doctor as Aldara cream has not been shown to be as effective in HIV positive patients.
  If you decide to have sexual relations while you still have warts, apply Aldara cream after – not before - sexual activity. Aldara cream may weaken condoms and diaphragms, therefore the cream should not be left on during sexual activity. Remember, Aldara cream does not protect against giving HIV or other sexually transmitted diseases to someone else.

- If you are being treated for basal cell carcinoma or actinic keratosis follow these additional precautions:
  Do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Aldara cream. Wear protective clothing and wide brimmed hats when outdoors.

Whilst using Aldara cream and until healed, the treatment area is likely to appear noticeably different
from normal skin.

Children and adolescents
Use in children and adolescents is not recommended.

Other medicines and Aldara cream
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
There are no medicines known to be incompatible with Aldara cream.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
You must tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of using Aldara cream during pregnancy. Studies in animals do not indicate direct or indirect harmful effects in pregnancy.

Do not breast-feed your infant during treatment with Aldara cream, as it is not known whether imiquimod is secreted in human milk.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.

Aldara cream contains methyl hydroxybenzoate, propyl hydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol
Methyl hydroxybenzoate (E 218) and propyl hydroxybenzoate (E 216) may cause allergic reactions (possibly delayed). Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 5 mg benzyl alcohol in each sachet. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. HOW TO USE ALDARA CREAM

Children and adolescents:
Use in children and adolescents is not recommended.

Adults:
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Wash hands carefully before and after applying the cream. Do not cover the treated area with bandages or other dressings after you have applied Aldara cream. Open a new sachet each time you use the cream. Dispose of any cream left in the sachet after use. Do not save the opened sachet for use at a later date.

The treatment frequency and duration differ for genital warts, basal cell carcinoma and actinic keratosis (see specific instructions for each indication).

ALDARA CREAM APPLICATION INSTRUCTIONS

- **<u>If you are being treated for genital warts:</u>**

Application Instructions – (Mon, Wed and Fri)
1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply a thin layer of Aldara cream onto clean, dry wart area and rub gently into the skin until cream vanishes.
4. After application of the cream, throw away the opened sachet and wash hands with soap and water.
5. Leave Aldara cream on the warts for 6 to 10 hours. Do not shower or bathe during this time.
6. After 6 to 10 hours wash the area where Aldara cream was applied with mild soap and water.

Apply Aldara cream 3 times per week. For example, apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover a wart area of 20 cm2 (approx. 3 square inches).

Men with warts under the foreskin should pull the foreskin back each day and wash underneath it (see section 2 “Warnings and precautions”).

Continue to use Aldara cream as instructed until your warts have completely gone (half the females who clear will do so in 8 weeks, half the males who clear will do so in 12 weeks but in some patients
warts may clear as early as 4 weeks).

Do not use Aldara cream for more than 16 weeks in the treatment of each episode of warts.

If you have the impression that the effect of Aldara cream is too strong or too weak, talk to your doctor or pharmacist.

- **<u>If you are being treated for basal cell carcinoma:</u>**

Application Instructions – (Mon, Tues, Wed, Thurs and Fri)
1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply Aldara cream to the affected area and 1cm (approx. 0.5 inch) around the affected area. Rub gently into the skin until the cream vanishes.
4. After application of the cream, throw away the opened sachet. Wash hands with soap and water.
5. Leave Aldara cream on the skin for about 8 hours. Do not shower or bathe during this time.
6. After about 8 hours, wash the area where Aldara cream was applied with mild soap and water.

Apply sufficient Aldara cream to cover the treatment area and 1 cm (about ½ an inch) around the treatment area each day for 5 consecutive days each week for 6 weeks. For example, apply the cream from Monday to Friday. Do not apply the cream on Saturday and Sunday.

- **<u>If you are being treated for actinic keratosis</u>**

Application Instructions – (Mon, Wed and Fri)
1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply the cream to the affected area. Rub gently into the area until the cream vanishes.
4. After application of the cream, throw away the opened sachet. Wash hands with soap and water.
5. Leave Aldara cream on the skin for about 8 hours. Do not shower or bathe during this time.
6. After about 8 hours, wash the area where Aldara cream was applied with mild soap and water.

Apply Aldara cream 3 times per week. For example, apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover an area of 25 cm2 (approx. 4 square inches).

Continue treatment for four weeks. Four weeks after finishing this first treatment, your doctor will assess your skin. If the lesions have not all disappeared, further four weeks of treatment may be necessary.

If you use more Aldara cream than you should
Wash the extra away with mild soap and water. When any skin reaction has gone you may then continue with your treatment.

If you accidentally swallow Aldara cream please contact your doctor.

If you forget to use Aldara cream
If you miss a dose, apply cream as soon as you remember and then continue in your regular schedule.
Do not apply the cream more than once per day.

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

4. POSSIBLE SIDE EFFECTS

The frequency of side effects is classified as follows:
Very common side effects (likely to occur in more than 1 in 10 patients)
Common side effects (likely to occur in fewer than 1 in 10 patients)
Uncommon side effects (likely to occur in fewer than 1 in 100 patients)
Rare side effects (likely to occur in fewer than 1 in 1,000 patients)
Very rare side effects (likely to occur in fewer than 1 in 10,000 patients).

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Aldara cream. Some patients have experienced changes in skin colour in the area where Aldara cream was applied. While these changes have tended to improve with time, in some patients they may be permanent. If your skin reacts badly when using Aldara cream, stop applying the cream, wash the area with mild soap and water and contact your doctor or pharmacist. In some individuals a lowering of blood counts was noted. A lowering of blood counts might make you more susceptible to infections, make you bruise more easily or cause fatigue. If you notice any of these symptoms, tell your doctor. Some patients who suffer from autoimmune disorders may experience worsening of their condition. If you notice any change during treatment with Aldara cream, tell your doctor. Serious skin reactions have been reported rarely. If you experience skin lesions or spots on your skin that start out as small red areas and progress to look like mini targets, possibly with symptoms such as itching, fever, overall ill feeling, achy joints, vision problems, burning, painful or itchy eyes and mouth sores, stop using Aldara cream and tell your doctor immediately. A small number of patients have experienced hair loss at the treatment site or surrounding area.

- <u>If you are being treated for genital warts:</u>

Many of the undesirable effects of Aldara cream are due to its local action on your skin.

Very common effects include redness (61% patients), wearing away of the skin (30% patients), flakiness and swelling. Hardening under the skin, small open sores, a crust that forms during healing, and small bubbles under the skin may also occur. You might also feel itching (32% patients), a burning sensation (26% patients) or pain in areas where you have applied Aldara cream (8% patients). Most of these skin reactions are mild and the skin will return to normal within about 2 weeks after stopping treatment.

Commonly some patients (4% or less) have experienced headache, uncommonly fevers and flu like symptoms joint and muscle pains; prolapse of the womb; pain on intercourse in females; erection difficulties; increase in sweating; feeling sick; stomach and bowel symptoms; ringing in the ears; flushing; tiredness; dizziness; migraine; pins and needles; insomnia; depression; loss of appetite; swollen glands; bacterial, viral and fungal infections (e.g. cold sores); vaginal infection including thrush; cough and colds with sore throat.

Very rarely severe and painful reactions have occurred, particularly when more cream has been used than recommended. Painful skin reactions at the opening of the vagina have very rarely made it difficult for some women to pass urine. If this occurs you should seek medical help immediately.

- <u>If you are being treated for basal cell carcinoma:</u>

Many of the undesirable effects of Aldara cream are due to its local action on your skin. Local skin reactions can be a sign that the drug is working as intended.

Very Commonly the treated skin may be slightly itchy.
Common effects include: pins and needles, small swollen areas in the skin, pain, burning, irritation, bleeding, redness or rash.
If a skin reaction becomes too uncomfortable during treatment, speak to your doctor. He/she may advise you to stop applying Aldara cream for a few days (i.e. to have a short rest from treatment). If there is pus (matter) or other suggestion of infection, discuss this with your doctor. Apart from reactions in the skin, other common effects include swollen glands and back pain. Uncommonly some patients experience changes at the application site (discharge, inflammation, swelling, scabbing, skin breakdown, blisters, dermatitis) or irritability, feeling sick, dry mouth, flu-like symptoms and tiredness.

- If you are being treated for actinic keratosis

Many of the undesirable effects of Aldara cream are due to its local action on your skin. Local skin reactions can be a sign that the drug is working as intended.

Very commonly the treated skin may be slightly itchy.

Common effects include pain, burning, irritation or redness.
If a skin reaction becomes too uncomfortable during treatment, speak to your doctor. He/she may advise you to stop applying Aldara cream for a few days (i.e. to have a short rest from treatment).
If there is pus (matter) or other suggestion of infection, discuss this with your doctor. Apart from reactions in the skin, other common effects include headache, anorexia, nausea, muscle pain, joint pain and tiredness.

Uncommonly some patients experience changes at the application site (bleeding, inflammation, discharge, sensitivity, swelling, small swollen areas in the skin, pins and needles, scabbing, scarring, ulceration or a feeling of warmth or discomfort), or inflammation of the lining of the nose, stuffy nose, flu or flu-like symptoms, depression, eye irritation, swelling of the eyelid, throat pain, diarrhoea, actinic keratosis, redness, swelling of the face, ulcers, pain in extremity, fever, weakness or shivering.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in 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 ALDARA CREAM

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and on the sachet label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25 ºC.
- Discard any cream remaining in a sachet after use.
- Sachets should not be re-used once opened.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aldara cream contains
The active substance is imiquimod. Each sachet contains 12.5 mg of imiquimod in 250 mg cream (5 %).
100 mg cream contains 5 mg imiquimod.

Also contains: isostearic acid, benzyl alcohol, cetyl alcohol, stearyl alcohol, white soft paraffin, polysorbate 60, sorbitan stearate, glycerol, methyl hydroxybenzoate (E 218), propyl hydroxybenzoate (E 216), xanthan gum and purified water (see also section 2 “Aldara cream contains methyl hydroxybenzoate, propyl hydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol”).

What Aldara cream looks like and contents of the pack
Each Aldara 5% cream sachet contains 250 mg of a white to slightly yellow cream. Each box contains 12 single-use polyester/aluminium foil sachets.

Manufactured by
Swiss Caps GmbH, Grassingerstraße 9, 83043 Bad Aibling, Germany.

MEDA Pharma GmbH & Co. KG, Benzstraße 1, 61352 Bad Homburg, Germany.

Procured from within the EU by the Product Licence Holder:
MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

POM

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Leaflet dated 7th April 2022
Leaflet coded xxxxxxxxxxxxx

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To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Imiquimod 5% Cream

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, please ask your doctor or your pharmacist.
- 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 any get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Imiquimod 5% Cream but it will be referred to as Imiquimod cream throughout the remainder of this leaflet.

What is in this leaflet

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

1. WHAT IMIQUIMOD CREAM IS AND WHAT IT IS USED FOR

Imiquimod cream may be used for three different conditions. Your doctor may prescribe Imiquimod cream for the treatment of:

- Warts (condylomata acuminata) on the surface of the genitals (sexual organs) and around the anus (back passage)
- Superficial basal cell carcinoma.
- This is a common slow-growing form of skin cancer with a very small likelihood of spread to other parts of the body. It usually occurs in middle-aged and elderly people, especially those who are fair-skinned and is caused by too much sun exposure. If left untreated, basal cell carcinoma can disfigure, especially on the face – therefore early recognition and treatment are important.
- Actinic keratosis
  Actinic keratoses are rough areas of skin found in people who have been exposed to a lot of sunshine over the course of their lifetime. Some are skin coloured, others are greyish, pink, red or brown. They can be flat and scaly, or raised, rough, hard and warty. Imiquimod should only be used for flat actinic keratoses on the face and scalp in patients with a healthy immune system where your doctor has decided that Imiquimod is the most appropriate treatment for you.

Imiquimod cream helps your body´s own immune system to produce natural substances which help fight your basal cell carcinoma, actinic keratosis or the virus that has caused your warts.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE IMIQUIMOD CREAM

Do not use Imiquimod cream
- if you are allergic to imiquimod or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Imiquimod cream
- If you have previously used Imiquimod cream or other similar preparations tell your doctor before starting this treatment.
- If you suffer from autoimmune disorders
- If you have had an organ transplant
- Do not use Imiquimod cream until the area to be treated has healed after previous drug or surgical treatment.
- Avoid contact with the eyes, lips and nostrils. In the event of accidental contact, remove cream by rinsing with water.
- Do not apply the cream internally.
- Do not use more cream than your doctor has advised.
- Do not cover the treated area with bandages or other dressings after you have applied Imiquimod cream.
- If the treated site becomes too uncomfortable, wash the cream off with mild soap and water.
  As soon as the problem has stopped you may restart to apply the cream.
- Tell your doctor if you have an abnormal blood count.

Because of the way Imiquimod works, there is a possibility that the cream may worsen existing inflammation in the treatment area.
- If you are being treated for genital warts follow these additional precautions:
  Men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If not washed daily the foreskin may be more likely to show signs of tightness, swelling and wearing away of the skin and result in difficulty in pulling it back. If these symptoms occur, stop the treatment immediately and call your doctor.
  If you have open sores: do not start using Imiquimod cream until after the sores have healed.
  If you have internal warts: do not use Imiquimod cream in the urethra (the hole from which urine is passed), the vagina (birth canal), the cervix (internal female organ), or anywhere inside your anus (rectum).
  Do not use this medication for more than one course if you have problems with your immune system, either due to illness or because of the medicines you are already taking. If you think this applies to you talk to your doctor.
  If you are HIV positive you should inform your doctor as Imiquimod cream has not been shown to be as effective in HIV positive patients.
  If you decide to have sexual relations while you still have warts, apply Imiquimod cream after – not before - sexual activity. Imiquimod cream may weaken condoms and diaphragms, therefore the cream should not be left on during sexual activity. Remember, Imiquimod cream does not protect against giving HIV or other sexually transmitted diseases to someone else.

- If you are being treated for basal cell carcinoma or actinic keratosis follow these additional precautions:
  Do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Imiquimod cream. Wear protective clothing and wide brimmed hats when outdoors.

Whilst using Imiquimod cream and until healed, the treatment area is likely to appear noticeably different
from normal skin.

Children and adolescents
Use in children and adolescents is not recommended.

Other medicines and Imiquimod cream
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
There are no medicines known to be incompatible with Imiquimod cream.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
You must tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of using Imiquimod cream during pregnancy. Studies in animals do not indicate direct or indirect harmful effects in pregnancy.

Do not breast-feed your infant during treatment with Imiquimod cream, as it is not known whether imiquimod is secreted in human milk.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.

Imiquimod cream contains methyl hydroxybenzoate, propyl hydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol
Methyl hydroxybenzoate (E 218) and propyl hydroxybenzoate (E 216) may cause allergic reactions (possibly delayed). Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 5 mg benzyl alcohol in each sachet. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. HOW TO USE IMIQUIMOD CREAM

Children and adolescents:
Use in children and adolescents is not recommended.

Adults:
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Wash hands carefully before and after applying the cream. Do not cover the treated area with bandages or other dressings after you have applied Imiquimod cream. Open a new sachet each time you use the cream. Dispose of any cream left in the sachet after use. Do not save the opened sachet for use at a later date.

The treatment frequency and duration differ for genital warts, basal cell carcinoma and actinic keratosis (see specific instructions for each indication).

IMIQUIMOD CREAM APPLICATION INSTRUCTIONS

- **<u>If you are being treated for genital warts:</u>**

Application Instructions – (Mon, Wed and Fri)
1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply a thin layer of Imiquimod cream onto clean, dry wart area and rub gently into the skin until cream vanishes.
4. After application of the cream, throw away the opened sachet and wash hands with soap and water.
5. Leave Imiquimod cream on the warts for 6 to 10 hours. Do not shower or bathe during this time.
6. After 6 to 10 hours wash the area where Imiquimod cream was applied with mild soap and water.

Apply Imiquimod cream 3 times per week. For example, apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover a wart area of 20 cm2 (approx. 3 square inches).

Men with warts under the foreskin should pull the foreskin back each day and wash underneath it (see section 2 “Warnings and precautions”).

Continue to use Imiquimod cream as instructed until your warts have completely gone (half the females who clear will do so in 8 weeks, half the males who clear will do so in 12 weeks but in some patients
warts may clear as early as 4 weeks).

Do not use Imiquimod cream for more than 16 weeks in the treatment of each episode of warts.

If you have the impression that the effect of Imiquimod cream is too strong or too weak, talk to your doctor or pharmacist.

- **<u>If you are being treated for basal cell carcinoma:</u>**

Application Instructions – (Mon, Tues, Wed, Thurs and Fri)
1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply Imiquimod cream to the affected area and 1cm (approx. 0.5 inch) around the affected area. Rub gently into the skin until the cream vanishes.
4. After application of the cream, throw away the opened sachet. Wash hands with soap and water.
5. Leave Imiquimod cream on the skin for about 8 hours. Do not shower or bathe during this time.
6. After about 8 hours, wash the area where Imiquimod cream was applied with mild soap and water.

Apply sufficient Imiquimod cream to cover the treatment area and 1 cm (about ½ an inch) around the treatment area each day for 5 consecutive days each week for 6 weeks. For example, apply the cream from Monday to Friday.
Do not apply the cream on Saturday and Sunday.

- **<u>If you are being treated for actinic keratosis</u>**

Application Instructions – (Mon, Wed and Fri)
1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply the cream to the affected area. Rub gently into the area until the cream vanishes.
4. After application of the cream, throw away the opened sachet. Wash hands with soap and water.
5. Leave Imiquimod cream on the skin for about 8 hours. Do not shower or bathe during this time.
6. After about 8 hours, wash the area where Imiquimod cream was applied with mild soap and water.

Apply Imiquimod cream 3 times per week. For example, apply the cream on Monday, Wednesday and Friday. One sachet contains enough cream to cover an area of 25 cm2 (approx. 4 square inches).

Continue treatment for four weeks. Four weeks after finishing this first treatment, your doctor will assess your skin. If the lesions have not all disappeared, further four weeks of treatment may be necessary.

If you use more Imiquimod cream than you should
Wash the extra away with mild soap and water. When any skin reaction has gone you may then continue with your treatment.

If you accidentally swallow Imiquimod cream please contact your doctor.

If you forget to use Imiquimod cream
If you miss a dose, apply cream as soon as you remember and then continue in your regular schedule.
Do not apply the cream more than once per day.

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

4. POSSIBLE SIDE EFFECTS

The frequency of side effects is classified as follows:
Very common side effects (likely to occur in more than 1 in 10 patients)
Common side effects (likely to occur in fewer than 1 in 10 patients)
Uncommon side effects (likely to occur in fewer than 1 in 100 patients)
Rare side effects (likely to occur in fewer than 1 in 1,000 patients)
Very rare side effects (likely to occur in fewer than 1 in 10,000 patients).

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Imiquimod cream. Some patients have experienced changes in skin colour in the area where Imiquimod cream was applied. While these changes have tended to improve with time, in some patients they may be permanent. If your skin reacts badly when using Imiquimod cream, stop applying the cream, wash the area with mild soap and water and contact your doctor or pharmacist. In some individuals a lowering of blood counts was noted. A lowering of blood counts might make you more susceptible to infections, make you bruise more easily or cause fatigue. If you notice any of these symptoms, tell your doctor. Some patients who suffer from autoimmune disorders may experience worsening of their condition. If you notice any change during treatment with Imiquimod cream, tell your doctor. Serious skin reactions have been reported rarely. If you experience skin lesions or spots on your skin that start out as small red areas and progress to look like mini targets, possibly with symptoms such as itching, fever, overall ill feeling, achy joints, vision problems, burning, painful or itchy eyes and mouth sores, stop using Imiquimod cream and tell your doctor immediately. A small number of patients have experienced hair loss at the treatment site or surrounding area.

- <u>If you are being treated for genital warts:</u>

Many of the undesirable effects of Imiquimod cream are due to its local action on your skin.

Very common effects include redness (61% patients), wearing away of the skin (30% patients), flakiness and swelling. Hardening under the skin, small open sores, a crust that forms during healing, and small bubbles under the skin may also occur. You might also feel itching (32% patients), a burning sensation (26% patients) or pain in areas where you have applied Imiquimod cream (8% patients). Most of these skin reactions are mild and the skin will return to normal within about 2 weeks after stopping treatment.

Commonly some patients (4% or less) have experienced headache, uncommonly fevers and flu like symptoms joint and muscle pains; prolapse of the womb; pain on intercourse in females; erection difficulties; increase in sweating; feeling sick; stomach and bowel symptoms; ringing in the ears; flushing; tiredness; dizziness; migraine; pins and needles; insomnia; depression; loss of appetite; swollen glands; bacterial, viral and fungal infections (e.g. cold sores); vaginal infection including thrush; cough and colds with sore throat.

Very rarely severe and painful reactions have occurred, particularly when more cream has been used than recommended. Painful skin reactions at the opening of the vagina have very rarely made it difficult for some women to pass urine. If this occurs you should seek medical help immediately.

- <u>If you are being treated for basal cell carcinoma:</u>

Many of the undesirable effects of Imiquimod cream are due to its local action on your skin. Local skin reactions can be a sign that the drug is working as intended.

Very Commonly the treated skin may be slightly itchy.
Common effects include: pins and needles, small swollen areas in the skin, pain, burning, irritation, bleeding, redness or rash.
If a skin reaction becomes too uncomfortable during treatment, speak to your doctor. He/she may advise you to stop applying Imiquimod cream for a few days (i.e. to have a short rest from treatment). If there is pus (matter) or other suggestion of infection, discuss this with your doctor. Apart from reactions in the skin, other common effects include swollen glands and back pain. Uncommonly some patients experience changes at the application site (discharge, inflammation, swelling, scabbing, skin breakdown, blisters, dermatitis) or irritability, feeling sick, dry mouth, flu-like symptoms and tiredness.

- If you are being treated for actinic keratosis

Many of the undesirable effects of Imiquimod cream are due to its local action on your skin. Local skin reactions can be a sign that the drug is working as intended.

Very commonly the treated skin may be slightly itchy.

Common effects include pain, burning, irritation or redness.
If a skin reaction becomes too uncomfortable during treatment, speak to your doctor. He/she may advise you to stop applying Imiquimod cream for a few days (i.e. to have a short rest from treatment).
If there is pus (matter) or other suggestion of infection, discuss this with your doctor. Apart from reactions in the skin, other common effects include headache, anorexia, nausea, muscle pain, joint pain and tiredness.

Uncommonly some patients experience changes at the application site (bleeding, inflammation, discharge, sensitivity, swelling, small swollen areas in the skin, pins and needles, scabbing, scarring, ulceration or a feeling of warmth or discomfort), or inflammation of the lining of the nose, stuffy nose, flu or flu-like symptoms, depression, eye irritation, swelling of the eyelid, throat pain, diarrhoea, actinic keratosis, redness, swelling of the face, ulcers, pain in extremity, fever, weakness or shivering.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in 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 IMIQUIMOD CREAM

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and on the sachet label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25 ºC.
- Discard any cream remaining in a sachet after use.
- Sachets should not be re-used once opened.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Imiquimod cream contains
The active substance is imiquimod. Each sachet contains 12.5 mg of imiquimod in 250 mg cream (5 %).
100 mg cream contains 5 mg imiquimod.

Also contains: isostearic acid, benzyl alcohol, cetyl alcohol, stearyl alcohol, white soft paraffin, polysorbate 60, sorbitan stearate, glycerol, methyl hydroxybenzoate (E 218), propyl hydroxybenzoate (E 216), xanthan gum and purified water (see also section 2 “Imiquimod cream contains methyl hydroxybenzoate, propyl hydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol”).

What Imiquimod cream looks like and contents of the pack
Each Imiquimod 5% cream sachet contains 250 mg of a white to slightly yellow cream. Each box contains 12 single-use polyester/aluminium foil sachets.

Manufactured by
Swiss Caps GmbH, Grassingerstraße 9, 83043 Bad Aibling, Germany.

MEDA Pharma GmbH & Co. KG, Benzstraße 1, 61352 Bad Homburg, Germany.

Procured from within the EU by the Product Licence Holder:
MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

POM

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Leaflet dated 7th April 2022
Leaflet coded xxxxxxxxxxxxx

To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.