

Haldol® 5 mg/ml injection

(haloperidol)

2867
19.02.25[6]

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse

In this leaflet

1. What Haldol injection is and what it is used for
2. Before you are given Haldol injection
3. How Haldol injection is used
4. Possible side effects
5. How Haldol injection is stored
6. Further information

1. WHAT HALDOL INJECTION IS AND WHAT IT IS USED FOR

The name of your medicine is Haldol 5 mg/ml injection but will be referred to as Haldol injection throughout the leaflet.

Haldol injection contains a medicine called haloperidol. This belongs to a group of medicines called 'antipsychotics'.

Haldol injection is used for:

- Schizophrenia, psychoses, mania and behavioural problems in adults

These illnesses affect the way you think, feel or behave. They may make you:

- Feel confused
- See, hear or feel things that are not there (hallucinations)
- Believe things that are not true (delusions)
- Feel unusually suspicious (paranoia)
- Feel very excited, agitated, enthusiastic or hyperactive
- Feel very aggressive or violent

Haldol injection is also used to treat feelings of sickness or actually being sick (nausea and vomiting).

2. BEFORE YOU ARE GIVEN HALDOL INJECTION

Do not use Haldol injection if:

- You are allergic to anything in Haldol injection (listed in section 6 below)
- You have, or have had, certain types of heart disease which cause your heart to beat with an abnormal rhythm (arrhythmia) or unusually slowly
- You are taking any medicines that affect your heart beat
- Your doctor tells you that the level of potassium in your blood is too low
- You have Parkinson's disease
- Your doctor tells you that you have a condition that affects part of your brain called the 'basal ganglia'
- You are less aware of things around you or your reactions become slower

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before being given Haldol injection.

Take special care with Haldol injection

If you are elderly, as you may be more sensitive to the effects of Haldol.

If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

Check with your doctor before being given Haldol injection if you have:

- A heart problem or anyone in your close family has died suddenly of heart problems
 - Ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke
 - Lower than normal levels of minerals (electrolytes) in your blood. Your doctor will advise you
 - Not been eating properly for a long time
 - Liver or kidney problems
 - Epilepsy or any other problem that can cause fits (convulsions) as you may need more medicine to control them.
 - Depression
 - Problems with your thyroid gland
 - A non-cancerous tumour of the adrenal gland (phaeochromocytoma)
- You may need to be more closely monitored, and the amount of Haldol injection you are given may have to be altered.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before you are given Haldol injection.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haldol injection. The ECG measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of minerals (electrolytes) in your blood.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Special monitoring may be needed if you are taking lithium and Haldol injection at the same time.

Tell your doctor or nurse straight away and stop taking both medicines if you get:

- Confused, disoriented, a headache, balance problems and feel sleepy. These are signs of a serious condition

Haldol injection can affect the way the following types of medicine work

Tell your doctor if you are taking medicines for:

- Calming you down or helping you to sleep (tranquillisers)
- Illnesses that affect the way you think, feel or behave (antipsychotics or neuroleptics)
- Pain (strong pain killers)
- Changes in your heart beat or are taking medicines that affect your heart beat
- Coughs and colds
- Depression, such as 'tricyclic antidepressants' and 'tetracyclic antidepressants'
- Lowering blood pressure, such as guanethidine and methyl dopa
- Severe allergic reactions, such as adrenaline
- Parkinson's disease, such as levodopa
- Thinning the blood, such as phenindione

Talk to your doctor or nurse before being given Haldol injection if you are taking any of these medicines.

Certain medicines may affect the way that Haldol injection works

Tell your doctor if you are taking medicines for:

- Depression, such as fluoxetine and paroxetine
- Malaria, such as quinine and mefloquine
- Anxiety, such as buspirone
- Problems with your heart beat, such as quinidine, disopyramide and procainamide, amiodarone, sotalol and dofetilide
- Epilepsy, such as phenobarbital and carbamazepine
- Allergies, such as terfenadine
- Serious infections, such as rifampicin
- Lowering blood pressure, such as water tablets (diuretics)
- Infections such as sparfloxacin, moxifloxacin, erythromycin IV
- A fungal infection, such as ketoconazole

Your doctor may have to change your dose of Haldol injection.

Haldol injection and alcohol

Drinking alcohol while you are using Haldol injection might make you feel drowsy and less alert. This means you should be careful how much alcohol you drink.

Pregnancy and breast-feeding

Talk to your doctor before being given Haldol injection if you are pregnant, think you may be pregnant or might become pregnant. The following symptoms may occur in newborn babies of mothers that have used Haldol in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

You may still be able to use Haldol injection if your doctor thinks you need to.

Ask your doctor for advice before you breast-feed. This is because small amounts of the medicine may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Elderly

If you suffer from a disorder with related memory loss, you should talk first to your doctor, who will decide if you can be given Haldol and will explain the possible risks of its use.

Driving and using machines

This medicine may affect you being able to drive. Do not drive or use any tools or machines without discussing this with your doctor first.

3. HOW HALDOL INJECTION IS USED

Your doctor or nurse will inject Haldol injection into a muscle.

How much medicine you will be given

Your doctor will decide how much Haldol injection you need and for how long. Your doctor will adjust the dose to suit you. Your dose will depend on:

- Your age
- How serious your symptoms are
- Whether you have other medical problems
- How you have reacted to similar medicines in the past

Adults

- Your starting dose will normally be 5 mg (or 1 and 2 mg if you are having it for nausea and vomiting)
- Further doses may be given hourly, with a maximum dose of 20 mg a day

Children

- Haldol injection should not be used in children

Stopping Haldol injection

The medicine should be used for as long as your doctor has told you. It may be some time before you feel the full effect of the medicine.

Unless your doctor decides otherwise, Haldol injection will be stopped gradually. Stopping treatment suddenly may cause effects such as:

- Feeling sick (nausea) or being sick (vomiting)
- Difficulty sleeping

Always follow your doctor's instructions carefully.

If you miss a dose or have too much Haldol injection

A doctor or nurse will give this medicine to you, so it is unlikely that you will miss a dose or be given too much. If you are worried, tell the doctor or nurse.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Haldol injection can cause side effects, although not everybody gets them.

Tell your doctor or nurse straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- Sudden swelling of the face or throat. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction. This only happens in a small number of people
- A serious problem called 'neuroleptic malignant syndrome'. The signs may include:
 - Fast heart beat, changing blood pressure and sweating followed by fever
 - Faster breathing, muscle stiffness, reduced consciousness and coma
 - Raised levels of a protein in your blood (an enzyme called creatine phosphokinase)
 - This can occur in fewer than 1 in 1,000 people
- Your heart may beat abnormally (arrhythmia). An arrhythmia can cause your heart to stop beating (cardiac arrest). In elderly people with dementia, a small increase in the number of deaths have been reported for patients taking neuroleptics compared with those not receiving neuroleptics. The precise frequency of how often this occurs is not known.
- Jerky movements and problems such as slowness, muscle stiffness, trembling and feeling restless. More saliva than normal, twitching or unusual movements of the tongue, face, mouth, jaw or throat, or rolling of the eyes. If you get any of these effects, you may be given an additional medicine

Tell your doctor or nurse if you notice or suspect any of the following side effects:

- Feeling agitated or having difficulty sleeping
- Headache

These can affect more than 1 in 10 people

- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk
- Feeling restless, low or depressed or sleepy
- Feeling light headed or dizzy, particularly when standing up
- Symptoms of psychosis such as abnormal thoughts or visions, or hearing abnormal sounds
- Problems with sight including blurred vision and rapid eye movements

These can occur in fewer than 1 in 10 people

- Liver problems including yellowing of the skin and eyes, pale stools and dark coloured urine
- Feeling confused
- A fall in the number of white blood cells which can cause frequent infections
- Fits or seizures (convulsions)
- Difficulty breathing or wheezing
- Hormone changes which may lead to:
 - Changes in weight
 - Difficulties with sex such as erection problems
- Some men experiencing swelling of their breast or painful and prolonged erection
- Some people losing interest in sex
- Some women having irregular, painful or heavy periods or no monthly period
- Some women unexpectedly producing breast milk, having painful breasts

These can occur in fewer than 1 in 100 people

- Being unable to open mouth

This can occur in fewer than 1 in 1000 people

- Bleeding or bruising more easily than normal. This can be caused by a fall in the number of small blood cells called platelets
- Fluid retention affecting the brain, resulting in weakness, tiredness or confusion

The precise frequency of how often these occur is not known

Other side effects

Common side effects (affects fewer than 1 in 10 people)

- Rash
- Slow movements
- Dry mouth
- Feeling sick, being sick
- Constipation
- Difficulty passing water (urine)
- Reactions at the site of injection

Uncommon side effects (affects fewer than 1 in 100 people)

- Sensitivity of skin to sunlight
- Sweating more than usual
- Fever
- Swelling of the ankles

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as **unknown**:

- Flaking or peeling of the skin
- Inflamed skin (red, hot to the touch and tender)
- Low body temperature
- In newborn babies, of mothers that have used Haldol in the last trimester (last three months of pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Test results:

- Abnormal test results for liver function
- Low blood sugar levels (hypoglycaemia)
- Abnormal heart traces (electrocardiogram, 'ECG')

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW HALDOL INJECTION IS STORED

Haldol injection is stored:

- Out of the sight and reach of children
- In its outer carton in order to protect it from light

Use solution immediately after opening/dilution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Haldol injection should not be used after the expiry date which is stated on the carton and ampoule label. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

One ml of solution contains 5 mg haloperidol.

The other ingredients are lactic acid and water for injection.

What Haldol injection looks like and contents of the pack

Haldol injection is supplied in amber glass ampoules containing 1 ml of clear, colourless solution. The ampoules are supplied in packs of 5 and 10.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by
Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340 Beerse, Belgium.

Essential Pharma Limited, Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070, Malta.

Procured from within the EU by Product Licence holder
Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex
HA1 1XD. Repackaged by Servipharm Ltd.

POM PL 20636/2867

Leaflet revision and issue date (Ref) 19.02.25[6]
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Blind or partially sighted?

Is this leaflet hard to see or read?

Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

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Haloperidol injection contains a medicine called haloperidol. This belongs to a group of medicines called 'antipsychotics'.

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- Feel very excited, agitated, enthusiastic or hyperactive
- Feel very aggressive or violent

Haloperidol injection is also used to treat feelings of sickness or actually being sick (nausea and vomiting).

2. BEFORE YOU ARE GIVEN HALOPERIDOL INJECTION

Do not use Haloperidol injection if:

- You are allergic to anything in Haloperidol injection (listed in section 6 below)
- You have, or have had, certain types of heart disease which cause your heart to beat with an abnormal rhythm (arrhythmia) or unusually slowly
- You are taking any medicines that affect your heart beat
- Your doctor tells you that the level of potassium in your blood is too low
- You have Parkinson's disease
- Your doctor tells you that you have a condition that affects part of your brain called the 'basal ganglia'
- You are less aware of things around you or your reactions become slower

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before being given Haloperidol injection.

Take special care with Haloperidol injection

If you are elderly, as you may be more sensitive to the effects of Haloperidol.

If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

Check with your doctor before being given Haloperidol injection if you have:

- A heart problem or anyone in your close family has died suddenly of heart problems
 - Ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke
 - Lower than normal levels of minerals (electrolytes) in your blood. Your doctor will advise you
 - Not been eating properly for a long time
 - Liver or kidney problems
 - Epilepsy or any other problem that can cause fits (convulsions) as you may need more medicine to control them.
 - Depression
 - Problems with your thyroid gland
 - A non-cancerous tumour of the adrenal gland (phaeochromocytoma)
- You may need to be more closely monitored, and the amount of Haloperidol injection you are given may have to be altered.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before you are given Haloperidol injection.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haloperidol injection. The ECG measures the electrical activity of your heart.

Blood tests

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Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Special monitoring may be needed if you are taking lithium and Haloperidol injection at the same time. Tell your doctor or nurse straight away and stop taking both medicines if you get:

- Confused, disoriented, a headache, balance problems and feel sleepy. These are signs of a serious condition

Haloperidol injection can affect the way the following types of medicine work

Tell your doctor if you are taking medicines for:

- Calming you down or helping you to sleep (tranquillisers)
- Illnesses that affect the way you think, feel or behave (antipsychotics or neuroleptics)
- Pain (strong pain killers)
- Changes in your heart beat or are taking medicines that affect your heart beat
- Coughs and colds
- Depression, such as 'tricyclic antidepressants' and 'tetracyclic antidepressants'
- Lowering blood pressure, such as guanethidine and methyl dopa
- Severe allergic reactions, such as adrenaline
- Parkinson's disease, such as levodopa
- Thinning the blood, such as phenindione

Talk to your doctor or nurse before being given Haloperidol injection if you are taking any of these medicines.

Certain medicines may affect the way that Haloperidol injection works

Tell your doctor if you are taking medicines for:

- Depression, such as fluoxetine and paroxetine
- Malaria, such as quinine and mefloquine
- Anxiety, such as buspirone
- Problems with your heart beat, such as quinidine, disopyramide and procainamide, amiodarone, sotalol and dofetilide
- Epilepsy, such as phenobarbital and carbamazepine
- Allergies, such as terfenadine
- Serious infections, such as rifampicin
- Lowering blood pressure, such as water tablets (diuretics)
- Infections such as sparfloxacin, moxifloxacin, erythromycin IV
- A fungal infection, such as ketoconazole

Your doctor may have to change your dose of Haloperidol injection.

Haloperidol injection and alcohol

Drinking alcohol while you are using Haloperidol injection might make you feel drowsy and less alert. This means you should be careful how much alcohol you drink.

Pregnancy and breast-feeding

Talk to your doctor before being given Haloperidol injection if you are pregnant, think you may be pregnant or might become pregnant. The following symptoms may occur in newborn babies of mothers that have used Haloperidol in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

You may still be able to use Haloperidol injection if your doctor thinks you need to.

Ask your doctor for advice before you breast-feed. This is because small amounts of the medicine may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Elderly

If you suffer from a disorder with related memory loss, you should talk first to your doctor, who will decide if you can be given Haloperidol and will explain the possible risks of its use.

Driving and using machines

This medicine may affect you being able to drive. Do not drive or use any tools or machines without discussing this with your doctor first.

3. HOW HALOPERIDOL INJECTION IS USED

Your doctor or nurse will inject Haloperidol injection into a muscle.

How much medicine you will be given

Your doctor will decide how much Haloperidol injection you need and for how long. Your doctor will adjust the dose to suit you. Your dose will depend on:

- Your age
- How serious your symptoms are
- Whether you have other medical problems
- How you have reacted to similar medicines in the past

Adults

- Your starting dose will normally be 5 mg (or 1 and 2 mg if you are having it for nausea and vomiting)
- Further doses may be given hourly, with a maximum dose of 20 mg a day

Children

- Haloperidol injection should not be used in children

Stopping Haloperidol injection

The medicine should be used for as long as your doctor has told you. It may be some time before you feel the full effect of the medicine.

Unless your doctor decides otherwise, Haloperidol injection will be stopped gradually. Stopping treatment suddenly may cause effects such as:

- Feeling sick (nausea) or being sick (vomiting)
- Difficulty sleeping

Always follow your doctor's instructions carefully.

If you miss a dose or have too much Haloperidol injection

A doctor or nurse will give this medicine to you, so it is unlikely that you will miss a dose or be given too much. If you are worried, tell the doctor or nurse.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Haloperidol injection can cause side effects, although not everybody gets them.

Tell your doctor or nurse straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- Sudden swelling of the face or throat. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction. This only happens in a small number of people
- A serious problem called 'neuroleptic malignant syndrome'. The signs may include:
 - Fast heart beat, changing blood pressure and sweating followed by fever
 - Faster breathing, muscle stiffness, reduced consciousness and coma
 - Raised levels of a protein in your blood (an enzyme called creatine phosphokinase)This can occur in fewer than 1 in 1,000 people
- Your heart may beat abnormally (arrhythmia). An arrhythmia can cause your heart to stop beating (cardiac arrest). In elderly people with dementia, a small increase in the number of deaths have been reported for patients taking neuroleptics compared with those not receiving neuroleptics. The precise frequency of how often this occurs is not known.
- Jerky movements and problems such as slowness, muscle stiffness, trembling and feeling restless. More saliva than normal, twitching or unusual movements of the tongue, face, mouth, jaw or throat, or rolling of the eyes. If you get any of these effects, you may be given an additional medicine

Tell your doctor or nurse if you notice or suspect any of the following side effects:

- Feeling agitated or having difficulty sleeping
- Headache

These can affect more than 1 in 10 people

- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk
- Feeling restless, low or depressed or sleepy
- Feeling light headed or dizzy, particularly when standing up
- Symptoms of psychosis such as abnormal thoughts or visions, or hearing abnormal sounds
- Problems with sight including blurred vision and rapid eye movements

These can occur in fewer than 1 in 10 people

- Liver problems including yellowing of the skin and eyes, pale stools and dark coloured urine
- Feeling confused
- A fall in the number of white blood cells which can cause frequent infections
- Fits or seizures (convulsions)
- Difficulty breathing or wheezing
- Hormone changes which may lead to:
 - Changes in weight
 - Difficulties with sex such as erection problems
- Some men experiencing swelling of their breast or painful and prolonged erection
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- Some women having irregular, painful or heavy periods or no monthly period
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These can occur in fewer than 1 in 100 people

- Being unable to open mouth

This can occur in fewer than 1 in 1000 people

- Bleeding or bruising more easily than normal. This can be caused by a fall in the number of small blood cells called platelets
- Fluid retention affecting the brain, resulting in weakness, tiredness or confusion

The precise frequency of how often these occur is not known

Other side effects

Common side effects (affects fewer than 1 in 10 people)

- Rash
- Slow movements
- Dry mouth
- Feeling sick, being sick
- Constipation
- Difficulty passing water (urine)
- Reactions at the site of injection

Uncommon side effects (affects fewer than 1 in 100 people)

- Sensitivity of skin to sunlight
- Sweating more than usual
- Fever
- Swelling of the ankles

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as **unknown**:

- Flaking or peeling of the skin
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- Abnormal test results for liver function
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Reporting of side effects

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Haloperidol injection is stored:

- Out of the sight and reach of children
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Haloperidol injection should not be used after the expiry date which is stated on the carton and ampoule label. The expiry date refers to the last day of that month.

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One ml of solution contains 5 mg haloperidol.

The other ingredients are lactic acid and water for injection.

What Haloperidol injection looks like and contents of the pack

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MANUFACTURER AND PRODUCT LICENCE HOLDER

Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340 Beerse, Belgium.

Essential Pharma Limited, Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070, Malta.

Procured from within the EU by Product Licence holder
Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex
HA1 1XD. Repackaged by Servipharm Ltd.

POM PL 20636/2867

Leaflet revision and issue date (Ref) 19.02.25[6]

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