Haldol™ decanoate 50mg/ml and 100mg/ml Solution for Injection

Haloperidol decanoate

Haldol is a trademark of Janssen-Cilag Ltd

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

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1. What Haldol decanoate is and what it is used for

The name of your medicine is Haldol decanoate.

Haldol decanoate contains a medicine called haloperidol decanoate. This belongs to a group of medicines called ‘neuroleptics’.

Haldol decanoate is used for illnesses affecting the way you think, feel or behave. These illnesses 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

2. Before you are given Haldol decanoate

Do not use Haldol decanoate if:
- You are allergic to sesame oil. Haldol decanoate contains sesame oil. See ‘Important information about some of the ingredients of Haldol decanoate’ below
- You are allergic to the active substance haloperidol or other similar medications (butoyrophenones) or to any of the other ingredients of Haldol decanoate (listed in section 6 below)
- You have ever had an irregular heart beat (arrhythmia) or unusually slow heart beat (bradycardia)
You have low levels of potassium in your blood
You suffer from a heart problem known as ‘QT-prolongation’. This problem sometimes runs in families and can only be confirmed by an electrocardiogram (ECG). An ECG measures the electrical activity of your heart
Your doctor tells you that you have a condition that affects part of your brain called the ‘basal ganglia’
You have Parkinson’s disease
You are less aware of things around you or your reactions become slower caused by taking other medicines or alcohol

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

**Take special care with Haldol decanoate**
Take special care with Haldol Decanoate 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 decanoate 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)
- Ever suffered from alcohol abuse
- 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 decanoate 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 decanoate.

**Medical check ups**
Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haldol decanoate. 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 decanoate 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 decanoate 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 such as chlorpromazine or neuroleptics)
- Pain (strong pain killers)
- Regulating your heart beat
- Coughs and colds
- Depression, such as ‘tricyclic 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 decanoate if you are taking any of these medicines.

**Certain medicines may affect the way that Haldol decanoate works**

Tell your doctor if you are taking medicines for:
- Depression, such as fluoxetine, paroxetine, fluvoxamine and sertraline
- Malaria, such as quinine and mefloquine
- Anxiety, such as buspirone and alprazolam
- Problems with your heart beat, such as quinidine, disopyramide and proca inamide, 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 spar floxac in, moxifloxacin, erythromycin IV
- Certain fungal infections, such as ketoconazole anditraconazole

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

**Haldol decanoate and alcohol**

Drinking alcohol while you are using Haldol decanoate 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 decanoate 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 decanoate 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 decanoate 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 Decanoate 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.

Important information about some of the ingredients of Haldol decanoate
Haldol decanoate contains sesame oil. This may rarely cause severe allergic
reactions. See ‘Do not use Haldol decanoate if’ above.

3. How Haldol decanoate is used
Your doctor or nurse will inject Haldol decanoate deep into a muscle. A single dose
will normally last for one month.

How much medicine will you be given
Your doctor will decide how much Haldol decanoate 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 50 mg every 4 weeks
• Your doctor may increase the dose by 50 mg every 4 weeks
• The dose may be increased to 200 mg every 4 weeks. In some cases higher
doses might be needed

The dose will be halved if your doctor thinks you should have the medicine every 2
weeks.

Children
• Haldol decanoate should not be used in children

Elderly people
• Elderly people are normally started on a lower dose
• The dose is usually 12.5 mg to 25 mg every 4 weeks

Always follow your doctor’s instructions carefully.

If you miss a dose or have too much Haldol decanoate
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 decanoate 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.

- 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). Unexplained sudden deaths have occurred rarely in patients taking this type of medicine
- In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.
- 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
- 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

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
- Changes in weight
- Difficulties with sex such as erection problems

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
• Some women unexpectedly producing breast milk, having painful breasts
• Loss of interest in sex
• Irregular, painful or heavy periods or no monthly period
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
• Some men experiencing swelling of their breast or painful and prolonged erection
• A change in the secretion of a hormone called antidiuretic hormone which can cause 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 their frequency is not known:
• Flaking or peeling of the skin
• Inflamed skin (red, hot to the touch and tender)
• Low body temperature
• Abscess at the site of injection
• In newborn babies of mothers that have used Haldol decanoate 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’)

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or nurse.
5. How Haldol decanoate is stored

Keep out of the reach and sight of children.

Keep the ampoule in the outer carton in order to protect it from light.

Do not store above 25°C. Do not refrigerate or freeze.

Do not use Haldol decanoate after the expiry date which is stated on the label after the abbreviation 'EXP:' and on the carton after 'Expiry:'. The expiry date refers to the last day of that month.

If stored for long periods in the cold, solid particles may form in Haldol decanoate. These may disappear when stored at room temperature. If these particles do not disappear, the ampoule should be thrown away.

Warming the ampoule in the hands may aid the withdrawal of the contents.

Haldol decanoate ampoules are for single use only. Any unused contents should be discarded immediately after use.

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. Further information

The active substance in Haldol decanoate is haloperidol decanoate. Haldol decanoate comes in two strengths:

50mg: Each ml of solution contains 70.52 mg of haloperidol decanoate equivalent to 50 mg/ml of haloperidol

100mg: Each ml of solution contains 141.04mg of haloperidol decanoate equivalent to100 mg/ml of haloperidol.

The other ingredients are benzyl alcohol (15 mg/ml) and sesame oil.

What Haldol decanoate looks like and contents of the pack

Haldol decanoate is a solution for injection. It is supplied in glass ampoules containing 1 ml of slightly amber, slightly viscous oily solution. The ampoules are supplied in packs of 5.

The marketing authorisation is held by: JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

Haldol decanoate is made by: GlaxoSmithKline Manufacturing S.p.A. Strada Provinciale Asolana N. 90 (loc. San Polo) 43056 Torrile (PR) Italy

OR

McGregor Cory Ltd, Exel, Middleton Close, Banbury, Oxfordshire, OX16 8RS, UK

For information in large print, tape, CD or Braille, telephone 1800 709 122.

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