

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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# Haloperidol

2 mg Tablets; 10mg Tablets

## HALOPERIDOL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or 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 you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### What is in this leaflet?

1. What Haloperidol tablets are and what they are used for
2. Before you take Haloperidol tablets
3. How to take Haloperidol tablets
4. Possible side effects
5. How to store Haloperidol tablets

#### *1. WHAT HALOPERIDOL TABLETS ARE AND WHAT THEY ARE USED FOR*

Haloperidol tablets contain a medicine called haloperidol. This belongs to a group of medicines called 'antipsychotics'.

#### **Haloperidol tablets are used for:**

- Schizophrenia, psychoses, mania and behavioural problems in adults and children
- 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

#### **Haloperidol tablets are also used for:**

- Gilles de la Tourette syndrome and movements you can't control (tics)
- Hiccups that won't go away

## 2. BEFORE YOU TAKE HALOPERIDOL TABLETS

### **Do not take Haloperidol tablets if:**

- You are allergic to anything in Haloperidol tablets
- 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 which 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 take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Haloperidol tablets.

### **Take special care with Haloperidol tablets**

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.

- Pain (strong pain killers)
- Changes in your heart beat or are taking medicines that affect your heart beat
- Coughs and colds
- Epilepsy
- Depression, such as 'tricyclic antidepressants' and 'tetracyclic antidepressants'
- Lowering blood pressure, such as guanethidine and methyldopa
- Severe allergic reactions, such as adrenaline
- Parkinson's disease, such as levodopa
- Thinning the blood, such as phenindione

Talk to your doctor before taking Haloperidol tablets if you are taking any of these medicines.

Certain medicines may affect the way that Haloperidol tablets work

### **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 tablets.

### ***Taking Haloperidol tablets with food and alcohol***

You can take Haloperidol tablets with or without food. Swallow the tablets with some water.

Drinking alcohol while you are taking Haloperidol tablets 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 taking Haloperidol tablets 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 take Haloperidol tablets if your doctor thinks you need to. Do not take this medicine if you are breast-feeding. This is because small amounts 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.

Available safety data in the paediatric population indicate a risk of extrapyramidal symptoms, including tardive dyskinesia (involuntary, repetitive body movements), and sedation. No long-term safety data are available.

Check with your doctor or pharmacist before taking Haloperidol tablets 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 have ever had 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***

tablets you take may have to be altered. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Haloperidol tablets.

### ***Medical check ups***

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Haloperidol tablets. 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 pharmacist 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 tablets at the same time. Tell your doctor straight away and stop taking both medicines if you get:

- Fever you can't explain or movements you can't control
- Confused, disoriented, a headache, balance problems and feel sleepy.

These are signs of a serious condition

Haloperidol tablets 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)

### **3. HOW TO TAKE HALOPERIDOL TABLETS**

Always take Haloperidol tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **How much should you take**

Your doctor will tell you how many Haloperidol tablets to take and for how long. Your doctor will adjust the dose to suit you. It is very important you take the correct amount.

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**

- When used to treat schizophrenia, psychoses or mania your dose will normally be 2mg, but may be increased up to 20mg
- When used to treat agitation and behavioural problems your dose will normally be 1.5 mg to 5mg
- It may be given as a single dose or split into smaller doses and given two to three times a day
- Your doctor may reduce the dose of Haloperidol tablets when your symptoms begin to improve

#### **Children**

- The dose for children depends on their weight and age
- The following doses will be split into smaller doses and given two to three times a day

#### **Children aged 3 to 12 years**

- When used to treat childhood schizophrenia, the normal dose will be 1 to 4mg a day but may be increased up to 6 mg a day
- When used to treat agitation and behavioural problems, the normal dose will be 0.5 to 3 mg a day but may be increased up to 3 mg a day

#### **Adolescents aged 13 to 17 years of age**

- When used to treat childhood schizophrenia, the normal dose will be 1 to 6 mg a day but may be increased up to 10 mg a day
- When used to treat agitation and behavioural problems, the normal dose will be 2 to 6 mg a day but may be increased up to 6 mg a day

#### **Elderly people**

- Elderly people are normally started on half the adult dose

- The amount of Haloperidol tablets you take will then be adjusted until the doctor finds the dose that suits you best

### **Taking Haloperidol tablets**

- Haloperidol tablets should be taken by mouth
- Swallow the tablets with some water

### **When to stop taking Haloperidol tablets**

Take the medicine 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 tells you otherwise, you should stop taking Haloperidol tablets 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 take more Haloperidol tablets than you should**

If you take more Haloperidol tablets than you were told to or if someone else has taken any Haloperidol tablets, talk to a doctor or go to the nearest hospital casualty department straight away.

### **If you forget to take Haloperidol tablets**

- If you forget to take a dose, take your next dose as usual. Then keep taking your medicine as your doctor has told you
- Do not take a double dose

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Haloperidol tablets 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
- Feeling sick, being sick
- Constipation
- Difficulty passing water (urine)

**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 Haloperidol 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.

By reporting side effects, you help provide more information on the safety of this medicine.

## 5. HOW TO STORE HALOPERIDOL TABLETS

### **Expiry Date**

Do not use this medicine after the expiry date shown on the carton label or blister strip.

If your doctor tells you to stop taking this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal.

Only keep this medicine, if your doctor tells you to.

If your tablets become discoloured or show any other signs of deterioration, consult your pharmacist (chemist) who will tell you what to do.

### **Storing your Medicine**

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not take your tablets out of the blister strip until it is time to take your dose.

### **IMPORTANT**

Remember this medicine is for you. Only a doctor can prescribe it. Never give your medicine to other people. It may harm them, even if their symptoms are the same as yours.

This leaflet does not tell you everything about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist (chemist). He/she will have additional information about this medicine and will be able to advise you.

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.

- 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

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