

**PATIENT INFORMATION LEAFLET**  
**HALOPERIDOL 0.5mg, 1.5mg, 5mg, 10mg, 20mg TABLETS**

**Read all of this leaflet carefully before you start taking this medicine.**

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Haloperidol Tablets contain the active ingredient haloperidol, which belongs to a class of drugs called neuroleptics. It improves the symptoms of:

- Major mental disorders (schizophrenia, paranoia, mania and hypomania)
- Behavioural or mental disorders, including those with mental retardation, such as aggression, hyperactivity and self-mutilation
- Moderate to severe restlessness with mental distress, excitement, violent or dangerous impulsive behaviour
- Gilles de la Tourette's syndrome and severe tic movements
- Restlessness and agitation in elderly patients
- Childhood behaviour disorders, especially with associated hyper activity and aggression
- Anxiety (used short term).

**2. BEFORE YOU TAKE HALOPERIDOL TABLETS**

**DO NOT take Haloperidol Tablets if**

- You know that you are allergic to haloperidol or any of the other ingredients of Haloperidol Tablets (see section 6 of this leaflet)
  - You are suffering from a brain disorder causing tremors, rigidity and slowing of movement (Parkinson's disease)
  - You have recently had a heart attack, have severe heart failure or are being treated for an abnormal heart rhythm
  - You suffer from unusually slow heartbeat
  - Your doctor tells you that the level of potassium in your blood is too low
  - You suffer from a lesion that affects a specific part of the brain (called the basal ganglia)
  - You are suffering from depression of the central nervous system, which can result in decreased rate of breathing, decreased pulse rate, decreased alertness to loss of consciousness.
- Haloperidol should not be given to patients who are in a coma.

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.

**Take special care with Haloperidol Tablets if**

- You have a liver or kidney problem
- You suffer from high blood pressure due to a tumour near the kidney (a condition known as pheochromocytoma)
- You have problems with your thyroid gland
- You have heart problem or anyone in your close family has died suddenly of heart problems
- You suffer from fits (epilepsy) or you have a condition that might lead to (convulsions) fits (such as brain damage or alcohol withdrawal)
- 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
- You suffer from alcohol abuse
- You are elderly, as you may be more sensitive to the effects of haloperidol tablets
- You ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke
- You have lower than normal levels of minerals (electrolytes) in your blood
- You have not been eating properly
- You suffer from a mental disorder including schizophrenia. Withdrawal of Haloperidol tablets may be associated with withdrawal symptoms like nausea, vomiting, insomnia or recurrence of symptoms
- You are feeling depressed.

Even though some of the above may appear obvious, it is important that your doctor is aware if any of them apply to you.

**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, including medicines obtained without a prescription. The effects of these medicines may change, especially if you are taking:

- Antiarrhythmic drugs for irregular heart beats (e.g. quinidine, disopyramide, procainamide, amiodarone, sotalol, bretylium and dofetilide)
- Antimicrobials for treatment of infection (e.g. sparfloxacin, moxifloxacin, erythromycin)
- Tricyclic antidepressants (e.g. amitriptyline), maprotiline, venlafaxine, fluvoxamine, fluoxetine, sertraline, paroxetine for treatment of depression
- Antipsychotic drugs (e.g. phenothiazines, chlorpromazine, pimozide and sertindole)
- Antihistamines for allergic reactions (e.g. terfenadine, promethazine)
- Cisapride used for treatment of constipation
- Anti-malarial drugs (e.g. quinine and mefloquine)
- Diuretics (water pills)
- Antifungals (e.g. itraconazole and ketoconazole)
- Anti-anxiety drugs (e.g. buspirone, alprazolam)
- Anticonvulsants (e.g. carbamazepine, phenobarbital, sodium valproate)
- Rifampicin to treat tuberculosis (TB)
- Hypnotics, sedatives or pain killers
- Blood pressure lowering drugs (e.g. methyldopa, guanethidine)
- Levodopa (antiparkinson drug)
- Phenindione to thin your blood

- Lithium (for depression)
- Adrenaline (used to increase heart rate).

### **Taking Haloperidol Tablets with food and drink**

You should not drink alcohol whilst you are taking this medicine. Haloperidol Tablets can be taken with or without food.

### **Pregnancy and breast feeding**

Do not take Haloperidol Tablets if you are pregnant, think you may be pregnant or are planning to become pregnant, or while breast-feeding, unless your doctor decides that treatment is essential.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

### **Driving and using machines**

Haloperidol Tablets may make you feel drowsy or dizzy or give you blurred vision. You should not drive or use machines when you first start to take this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

### **Important information about some of the ingredients of Haloperidol Tablets**

This medicine also contains:

- Lactose which is a sugar. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicine
- E124 (ponceau 4R red) which may cause allergic reactions (found in the 10mg tablets only).

## **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.

Swallow the tablets with a glass of water.

Your doctor will decide on a suitable dose depending on your condition. The dosage should be low to begin with. Your doctor may want to increase the dosage gradually, until the best result is achieved.

#### **Adults:**

- *Major mental disorders, behavioural or mental disorders, moderate to severe restlessness with mental distress, impulsive behaviour:*

The usual starting dose is between 1.5mg and 20mg daily. The usual maintenance dose is between 3mg and 10mg daily

- *Gilles de la Tourette's syndrome:*

The usual starting dose is 2mg daily. The usual maintenance dose is usually 4mg daily

- *Anxiety:*

0.5mg twice daily

#### **Elderly:**

- Half of the usual adult dose may be sufficient.

#### **Children:**

A child's daily dose will be determined by bodyweight, divided in two doses to be taken in the morning and evening.

The pharmacist's label on your pack will tell you how many tablets you should take and how often you should take them. Please read the label carefully. Do not take more than your doctor has recommended.

### **If you stop taking Haloperidol Tablets**

- Continue to take Haloperidol Tablets even if you no longer feel ill. Do not stop taking this medicine without talking with your doctor first, especially if you have taken large doses for a long time. When the time comes to stop your doctor will probably decrease your dose gradually as stopping the tablets suddenly may cause ill-effects such as nausea (feeling sick), vomiting (being sick), sweating and difficulty in sleeping
- For mood disorders and schizophrenia, it may take several weeks for you to feel the full benefit of this medicine. If you stop taking this medicine suddenly, your symptoms may come back.

### **If you take more Haloperidol Tablets than you should**

If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Take this leaflet and any remaining tablets with you so that the medical staff know exactly what you have taken.

### **If you forget to take your Haloperidol Tablets**

If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before. Do not take more than one dose at a time.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Haloperidol Tablets can sometimes 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, swallowing or breathing problems. 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
- 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. If you notice any of these symptoms seek medical advice immediately
- Rarely patients may develop Neuroleptic Malignant Syndrome. This causes a high temperature, rigid muscles, drowsiness, occasional loss of consciousness and requires emergency admission to hospital for treatment
- 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 has been reported for patients taking neuroleptics compared with those not receiving neuroleptics.

**Tell your doctor straight away if you notice any of the following side effects:**

**Very common - (affects more than 1 in 10 people)**

- Agitation
- Difficulty in sleeping
- Headache
- Repetitive, involuntary muscle movements.

**Common - (affects less than 1 in 10 people)**

- Depression
- Constipation
- Decreased body movements
- Dry mouth, secretion of excess saliva, feeling sick (nausea), being sick (vomiting)
- Restlessness
- Spasmodic movement of the eyeballs

- Diminished facial expressions
- Abnormal liver function tests
- Increased tone of muscles, tremors
- Rash
- Dizziness
- Difficulty in passing urine
- Fall in blood pressure
- Problems with erection
- Visual disturbances
- Increase or decrease in weight.
- Drowsiness

**Uncommon - (affects less than 1 in 100 people)**

- You may suffer from a sore throat, high fever, feel very tired, become pale or develop bruises. These may indicate blood problems developing as a result of using this medicine
- Reaction to sunlight
- Itching
- Sweating
- Enlarged liver, jaundice (yellow discolouration of the eye or skin)
- Confusion
- Muscle Spasms, muscle stiffness
- Decreased or loss of sexual drive
- Abnormal neck movements
- Convulsions (fits)
- Lack of menstrual periods, painful periods, breast discomfort or pain, spontaneous flow of milk from the breast
- Impaired body movement
- Sedation
- Parkinsonism (characterised by tremor, rigidity or postural instability)
- Fever
- Increased heart rate
- Difficulty in walking
- Difficulty in breathing
- Fluid retention.

**Rare - (affects less than 1 in 1,000 people)**

- Raised prolactin (hormone) levels in the blood
- Inability to normally open the mouth
- ECG abnormalities.

**Other side effects include:**

- Low blood sugar levels
- Inappropriate antidiuretic hormone secretion
- Swelling or tightening of the throat
- Liver failure, biliary disorders
- Inflammation of the blood vessels characterised by fever, pain in the joints and muscles
- Scaling and redness of the skin
- Enlarged breasts in males
- Decreased body temperature.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of suspected adverse reactions:

You can help to make sure that medicines remain safe as possible by reporting any unwanted side effects via the internet at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Alternatively you can call freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

United Kingdom  
Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## **5. HOW TO STORE HALOPERIDOL TABLETS**

Keep out of the reach and sight of children.

Do not use Haloperidol Tablets after the expiry date which is stated on the box.

If your tablets are out of date, take them to your pharmacist who will get rid of them safely.

Do not store above 20°C. Store in the original package.

## **6. FURTHER INFORMATION**

Haloperidol Tablets are available in five strengths, containing either 0.5mg, 1.5mg, 5mg, 10mg or 20mg of the active substance Haloperidol.

Haloperidol Tablets also contains lactose, povidone, starch, magnesium stearate, stearic acid.

Haloperidol Tablets 5mg also contains dispersed green 18834.

Haloperidol Tablets 10mg also contains aerosil and ponceau 4R (E124).

### **What Haloperidol Tablets look like and contents of the pack**

Haloperidol Tablets 5mg are light green uncoated tablets.

Haloperidol Tablets 10mg are pink uncoated tablets.

Haloperidol Tablets 0.5mg, 1.5mg and 20mg are white uncoated tablets.

They may be packed in plastic securitainers of 25, 28, 50, 100, 250, 500 and 1000 tablets.

### **Marketing Authorisation Holder & Manufacturer:**

Mercury Pharmaceuticals Ltd

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