

ROYCE HALOPERIDOL TABLET

Haloperidol (1.5mg)

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What Royce Haloperidol Tablet 1.5mg is used for

It is indicated for:

- Psychotic disorders – severe mental disorders that cause abnormal thinking and perceptions.
- Tourette's syndrome – for the control of body movement and vocal utterances.
- Behaviour problems in children of combative, explosive hyperexcitability (which cannot be accounted for by immediate provocation).
- Short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood liability and poor frustration tolerance.

How Royce Haloperidol Tablet 1.5mg works

It works by changing the actions of chemicals in your brain.

The precise mechanism of action has not been clearly established.

Before you use Royce Haloperidol Tablet 1.5mg

-When you must not use it:

- If you are allergic to Haloperidol or any of the ingredients.
- If you have Parkinson's disease.
- If you are suffering from depression of the central nervous

system, which can result in decreased rate of breathing, decreased pulse rate, decrease alertness to loss of consciousness.

- Individual in coma state.
- If you are breastfeeding.

-Before you start to use it:

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Heart and blood vessel disorders including low blood pressure and worsening of chest pain.
- Excessive thyroid hormone.
- Pregnant or breastfeeding.
- In third semester of pregnancy.

-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. Your doctor may need to change the dose of the other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Haloperidol:

- Lithium (for mental illnesses).
- Anti-convulsant medication (for treatment of seizures).
- Anti-parkinson medication (for treatment of Parkinson's disease).
- Neuroleptic medicines (tranquillizer).

How to take Royce Haloperidol Tablet 1.5mg

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

-How much to use:

Adults:

Moderate symptom: 0.5mg – 2.0mg

Severe symptom: 3.0mg – 5.0mg

Elderly/debilitated: 0.5mg – 2.0mg

Long term/resistant: 3.0mg – 5.0mg

Children:

- Haloperidol is not intended for children under 3 years old

- **3 to 12 years (weight 15 – 40kg):**
- The total dose may be divided, to be given 2 or 3 times a day.
- 0.05mg/kg/day – 0.15mg/kg/day.

Maintenance Dosage:

Upon achieving a satisfactory therapeutic response, dosage should then gradually reduce to the lowest effective maintenance level.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased by your doctor.

-When to use it:

To be taken 2 or 3 times a day.

Your doctor will decide when it is appropriate for you to use Royce Haloperidol Tablet 1.5mg according to the type of condition you have. Take this tablet orally with a glass of water.

-How long to use it:

Continue taking the tablets for as long as doctor recommends unless you have any problems. In that case, check with your doctor.

-If you forget to use it:

- If you forget to take a dose, take it as soon as you remember.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

-If you use too much (overdose):

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You may need urgent medical attention.

Symptoms of overdosage may be an exaggeration of side effects, the most prominent of which would be:

- Severe extrapyramidal reactions.
- Sedation.
- Low blood pressure.

While you are using Royce Haloperidol Tablet 1.5mg

-Things you must do

If you become pregnant whilst taking Royce Haloperidol Tablet 1.5mg, tell your doctor.

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-Things you must not do

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

-Things to be careful of

- Avoid activities that require mental and/or physical alertness.
- Avoid the usage of alcohol.

Side Effects

Like all medicines, Royce Haloperidol Tablet 1.5mg can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Extrapyramidal reactions: occur frequently, especially during the first few days of therapy. Symptoms include parkinson symptoms, restlessness, unusual movements, such as trembling and shaking of the hands and fingers, twisting movements of the body.
- Withdrawal emergent neurological signs: usually occurs to people on maintenance treatment after abrupt withdrawal. Symptoms include repetitive, involuntary movements.
- Persistent Tardive Dyskinesia: usually occurs in people on long term therapy. The risks are greater in elderly, especially female. Symptoms include rhythmical involuntary movements of tongue, face, mouth or jaw (e.g., protrusion of tongue, puffing of cheeks, puckering of mouth, chewing movements).
- Other Central Nervous System Effects: sleeping difficulty, anxiety, intense happiness, agitation, drowsiness, depression, tiredness, headache, confusion, spinning sensation, seizures, hallucination (hear, smell, taste or feel things that do not exist).
- Cardiovascular effects: Excessively rapid heartbeat and low blood pressure.
- Hematologic effects: Changes in the number of white blood cells in the blood, decreases in red blood cell counts and deficiency of certain blood cells.
- Liver effects: Impaired liver function and/or yellowing of skin and eyes.

- Dermatologic reactions: Maculopapular (a flat, red area on the skin that is covered with small red bumps) and acne form skin reactions, overactive to lights and loss of hair.
- Endocrine disorders: Breast milk production, breast engorgement, pain in the breast, menstrual irregularities, abnormal enlargement of the breast in a male, impotence, increased sex drive, changes in level of glucose in the blood, and abnormally low concentration of sodium ions in blood.
- Gastrointestinal effects: Loss of appetite, constipation, diarrhoea, excessive production of saliva, indigestion, nausea and vomiting.
- Autonomic reactions: Dry mouth, blurred vision, urinary retention and excessive sweating.
- Respiratory effects: narrowing of airway or throat and increased breathing rate.

Advise to consult your doctor/pharmacist for further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:03-78835549 or visiting the website npra.moh.gov.my (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and disposal of Royce Haloperidol Tablet 1.5mg

-Storage:

Store in a dry place below 30°C. Protect from light. Keep container tightly closed. Keep out of reach and sight of children.

-Disposal:

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

Product description

-What it looks like:

Round yellow coloured, flat face, bevel edge tablet with 7.9mm diameter and breaking line on one side and plain on the other side.

-Ingredients:

-Active Ingredient:
Haloperidol

-Inactive Ingredients:

Corn Starch, Povidone, Magnesium Stearate, Colloidal Silicone Dioxide, Lactose, Colour Quinoline Yellow Lake and Sodium Lauryl Sulphate.

-MAL Number

MAL19861364AZ

Manufacturer and Product Registration Holder

Royce Pharma Manufacturing Sdn. Bhd.
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