

Package leaflet: information for the user

Revocon™ 25 mg Tablets

Tetrabenazine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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. See section 4.

What is in this leaflet

1. What Revocon tablets are and what they are used for
2. What you need to know before you take Revocon tablets
3. How to take Revocon tablets
4. Possible side effects
5. How to store Revocon tablets
6. Contents of the pack and other information

1. What Revocon tablets are and what they are used for

Revocon tablets are a medicine belonging to the group treating disorders of the nervous system.
Revocon tablets are used for the treatment of the jerky, irregular, uncontrollable movements of Huntington's chorea.

2. What you need to know before you take Revocon tablets

Do not take Revocon tablets

- if you are allergic to tetrabenazine or any of the other ingredients of this medicine (listed in section 6)
 - if you take reserpine (medicine to control high blood pressure and treat psychotic states)
 - if you take MAO inhibitors (medicine to treat depression, see also subsection 'Taking other medicines')
 - if you suffer from Parkinson-like symptoms
 - if you have depression
 - if you are breast-feeding
 - if you suffer from pheochromocytoma (tumour of the adrenal gland)
 - if you suffer from pro-lactin-dependent tumours, e.g. pituitary or breast cancer.
- Discuss this with your doctor if you are not sure.

Warnings and precautions

Talk to your doctor before taking Revocon tablets

- if you are pregnant
- if you have either kidney or liver problems
- if you have a heart condition known as long QT syndrome or if you have or have had any problems with your heart rhythm.

If you start to have mental changes such as confusion or hallucinations, or develop stiffness in your muscles and a fever or you sweat and have fluctuations in blood pressure, you may be developing a condition called Neuroleptic Malignant Syndrome. If you have these symptoms please contact your doctor straight away.

Other medicines and Revocon tablets

Revocon tablets interact with a large number of other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Your doctor will be careful if you take Revocon tablets together with
 - levodopa (a medicine used to treat Parkinson's disease)
 - drugs known to prolong the QTc interval including:
 - some drugs used to treat mental health conditions (e.g. chlorpromazine, thioridazine)
 - certain antibiotics (e.g. gatifloxacin, moxifloxacin)
 - some drugs used to treat problems with heart rhythm conditions (e.g. quinidine, procainamide, amiodarone, sotalol).
- You should not be given Revocon tablets together with reserpine.
- Any treatment with MAO inhibitors should be stopped 14 days before the treatment with tetrabenazine starts.
- Taking this medicine with certain types of antidepressants, alcohol, strong opioids (pain killers), beta blockers, antihypertensive drugs (medicine to treat high blood pressure), hypnotics and neuroleptics (medicine to treat psychotic disorders) is not recommended.
- Some medicines (e.g. fluoxetine, paroxetine, terbinafine, moclobemide and quinidine) may increase the level of tetrabenazine in the blood. If you are taking a combination of these drugs your doctor will monitor you carefully. A reduction of the tetrabenazine dose may be necessary.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Your doctor will decide after taking all risks and benefits into account, if you may use Revocon tablets during pregnancy.
Revocon tablets must not be taken by breast-feeding mothers.

Driving and using machines

Revocon tablets may cause drowsiness in some people. Do not drive or use machinery if you are affected.

Revocon tablets contain lactose

These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking the tablets.

3. How to take Revocon tablets

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

Swallow the tablet(s) with water or another non-alcoholic drink.

Adults

The dose that you need varies from person to person. The doctor will have decided on the dose you need. The following is just a guide.

The recommended starting dose is half a tablet (12.5 mg) one to three times a day. This can be increased every three or four days by half a tablet until the best effect is reached or if side effects such as sedation, Parkinsonism or depression are noticed.

The maximum daily dose is 8 tablets (200 mg) a day.
If you have taken the maximum dose for a period of seven days and your condition has not improved, you should talk to your doctor.

The elderly

The standard dosage has been taken by elderly patients without apparent ill effect. However, Parkinson-like side effects are common and may limit the dose you can take.

Use in children

The treatment is not recommended in children.

Patients with liver disorder

Patients with mild to moderate liver disorder should start with half a tablet a day. For patients with severe liver disorder, additional caution is necessary. Your doctor will decide on the dose to give you.

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Revocon™
25 mg Tablets
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Patients with kidney disorder

Revocon tablets are not recommended for use in this patient group.

If you take more Revocon tablets than you should

If you take more Revocon tablets than you should, you may develop drowsiness, sweating, low blood pressure, and extremely low body temperature (hypothermia). Your doctor will treat the signs.

If you forget to take Revocon tablets

If you forget to take one dose, you should never make up for the missing dose by taking a double dose next time. Just continue with the next dose when it is due.

If you stop taking Revocon tablets

Do not stop taking Revocon tablets unless your doctor tells you to. A Neuroleptic Malignant Syndrome (described in Section 2) has been described after abrupt withdrawal of tetrabenazine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious, very common side effects (affects more than 1 user in 10)

Revocon tablets can cause depression or Parkinson-like syndrome (uncontrollable movements of the hands, arms, legs and head, with higher dosages). If this happens you must tell your doctor.

Serious, rare side effects (affects 1 to 10 users in 10,000)

Contact your doctor immediately if you develop Neuroleptic Malignant Syndrome (described in Section 2).

Other side effects

Very common (affects more than 1 user in 10)
Drowsiness (with higher dosages).

Common (affects 1 to 10 users in 100)

Confusion, anxiety, sleeplessness, low blood pressure, dysphagia (difficulty in swallowing), nausea, vomiting, diarrhoea, constipation.

Uncommon (affects 1 to 10 users in 1,000)

Mental changes such as confusion or hallucinations, severe extrapyramidal symptoms such as stiff limbs or trembling hands, fever.

Very rare (affects less than 1 user in 10,000)

Muscle damage.

Not known (frequency cannot be estimated from the available data)

Disorientation, nervousness, ataxia and dystonia (loss of control of movements, poor posture), akathisia (restlessness), dizziness, forgetfulness, slow heart beat, stomach pain, dry mouth.

Reporting of side effects

If you get any of the side effects, talk to your doctor. 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 to store Revocon tablets

Keep this medicine out of the sight and reach of children, preferably in a locked cupboard or medicine cabinet.

Revocon tablets should be stored below 25°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Return any medicine left over to your pharmacist; only keep it if your doctor tells you to.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Revocon tablets contain**

- The active substance is tetrabenazine.
- Each tablet contains 25 mg tetrabenazine.
- The other ingredients are: lactose monohydrate, maize starch, microcrystalline cellulose, purified talc, magnesium stearate, colloidal anhydrous silica, sodium starch glycolate (type A), iron oxide yellow (E172).

What Revocon tablets look like and contents of the pack

Revocon tablets are light yellow, circular, flat tablets with a break line on one side and SUN on the other side. The tablets can be divided into equal halves.

Each bottle of Revocon tablets contains 112 tablets.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries BV
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

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