

Orphenadrine Hydrochloride 50mg/5ml Oral Solution

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 Orphenadrine Hydrochloride Oral Solution is and what is it used for
2. What you need to know before you take Orphenadrine Hydrochloride Oral Solution
3. How to take Orphenadrine Hydrochloride Oral Solution
4. Possible side effects
5. How to store Orphenadrine Hydrochloride Oral Solution
6. Contents of the pack and other information

1. What is Orphenadrine Hydrochloride Oral Solution and what is it used for

The name of your medicine is Orphenadrine Hydrochloride 50mg/5ml Oral Solution (called orphenadrine in this leaflet). It contains orphenadrine hydrochloride. This belongs to a group of medicines called anticholinergics.

Orphenadrine can be used for the symptoms of Parkinsonism (usually slow movement, muscle stiffness and shaking fingers). These symptoms can be caused by Parkinson's Disease, but there are other causes as well.

2. What you need to know before you take Orphenadrine Hydrochloride Oral Solution

Do not take Orphenadrine Hydrochloride Oral Solution if:

- You are allergic (hypersensitive) to orphenadrine or any of the other ingredients of this medicine (listed in section 6)
- You have an enlarged prostate gland, particularly if you are an elderly man
- You have problems with your movement and speech
- You have porphyria. This is a red blood cell problem that is passed through families
- You have difficulty passing water (urine)
- You have stomach problems including a paralysed bowel. The signs include swollen and tender stomach (abdomen), feeling and being sick but with no wind
- You have glaucoma (increased pressure in the eye)
- You are at risk of getting a very high temperature. This can happen if you have malaria

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 taking orphenadrine.

Warnings and precautions

Before you take orphenadrine tell your doctor if:

- You have unusual fast heart beats, high blood pressure or heart problems
- You have kidney or liver problems
- You are an older person
- You suffer from involuntary movements of the face or body (tardive dyskinesia).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking orphenadrine.

Continued overleaf

Children and adolescents

Do not give this medicine to children under 18 years because it does not work.

Other medicines and orphenadrine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because orphenadrine can affect the way some other medicines work. Also some medicines can affect the way orphenadrine works.

Tell your doctor if you are taking any of these medicines

- Painkillers such as dextropropoxyphene
- Anti-histamines - used for allergies
- Disopyramide - used for irregular heart beats
- Medicines used for depression
- Medicines used for mental problems called 'psychoses' (such as chlorpromazine and thioridazine)
- Medicines used for Parkinson's disease (such as amantadine - which can also be used to treat viral infections)
- Medicines used for stomach pain – "antispasmodics" (such as atropine sulphate, dicycloverine hydrochloride and propantheline bromide).

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.

Driving and using machines

While taking this medicine you may feel light-headed, your eyesight can become blurry or you could get an unusual feeling of excitement (elation). If this happens, you should not drive a car or use any tools or machines.

Orphenadrine Hydrochloride Oral Solution Contains

- Methyl Hydroxybenzoate (E218) and Propyl Hydroxybenzoate (E216). May cause allergic reactions (possibly delayed).
- Benzyl Alcohol. This medicine contains 1.03mg of benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
- Liquid Maltitol (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect. Calorific value 4.7 kcal/5ml
- Sorbitol (E420). This medicine contains 454.7mg sorbitol in each 5ml. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.
- Ethanol (alcohol). This medicine contains 0.7 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'.

3. How to take Orphenadrine Hydrochloride Oral Solution

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

Taking this medicine

- This medicine contains 50mg of orphenadrine hydrochloride in each 5ml
- Take this medicine by mouth.

Adults

The usual doses for adults are given below:

Parkinsonism

- A total daily dose of 100mg to 400mg each day
- This total daily dose can be split into two or three smaller doses to be taken through the day
- At the start of treatment you may be asked to take 150mg each day
- This total daily dose may be increased by 50mg every two to three days
The increases should be continued until your symptoms are under control.

Parkinsonism that happens after having encephalitis (brain infection) or where the cause is unknown

- 250mg to 300mg each day
- This can be split into two or three smaller doses to be taken through the day.

Parkinsonism that happens when your arteries harden

- 100mg to 150mg each day
- This can be split into two or three smaller doses to be taken through the day.

Parkinsonism that is caused by other medicines

- 150mg to 300mg each day
- This can be split into two or three smaller doses to be taken through the day.

Children

This medicine is not usually given to children.

Elderly

If you are an older person you may be more sensitive to the medicine. The chances of you getting side effects are increased.

If you take more Orphenadrine Hydrochloride Oral Solution than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. The following effects may happen: excitement, confusion, being delirious, unusually fast heart beats, pupils become larger, difficulty in passing urine, fits and coma.

If you forget to take Orphenadrine Hydrochloride Oral Solution

Do not take a double dose (two doses at the same time) to make up for forgotten doses. Skip the missed dose, then go on as before.

If you stop taking Orphenadrine Hydrochloride Oral Solution

Keep taking orphenadrine until your doctor tells you to stop. Do not stop taking your medicine suddenly.

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

4. Possible side effects

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

If you notice any of the following side effects, STOP taking the medicine and see a doctor immediately:

- any kind of skin rash, flaking skin, boils or sore lips and mouth
- sudden wheezing, fluttering or tightness of the chest or collapse

This may mean that you are having an allergic reaction to orphenadrine.

If you get any of the following side effects, see your doctor as soon as possible:

Common (affect more than 1 in 100 people)

- Blurred vision and dizziness.

Uncommon (affect more than 1 in 1000 people)

- Fast heart beats
- Difficulty in managing your movements
- Difficulty in passing urine
- Hallucinations
- Feeling confused
- Fits.

Tell your doctor if you get any of these side effects:

Common (affect more than 1 in 100 people)

- Dry mouth
- Feeling sick (nausea) and stomach upset
- Feeling restless.

Uncommon (affect more than 1 in 1000 people)

- Constipation
- Greater sensitivity to things around you or feeling nervous
- Feeling light-headed and an unusual feeling of excitement (elation)
- Difficulty sleeping or feeling tired.

Rare (affect more than 1 in 10,000 people)

- Forgetting things more than usual.

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Orphenadrine Hydrochloride Oral Solution

- Keep out of the reach and sight of children.
- Do not store above 25°C and keep out of direct sunlight.
- Do not use after the expiry date which is stated on the label and carton (exp: month, year)
- The expiry date refers to the last day of that month
- Do not use Orphenadrine Hydrochloride Oral Solution if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
- 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. Contents of the pack and other information

What Orphenadrine Hydrochloride Oral Solution contains

- The active ingredient is orphenadrine hydrochloride.
- The other ingredients are methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol (E1520), liquid maltitol (E965), sorbitol solution (E420), saccharin sodium, blackcurrant flavour (containing pulegone, benzyl alcohol, propylene glycol and ethanol), aniseed flavour, citric acid (E330), sodium citrate (E331) and purified water.

What Orphenadrine Hydrochloride Oral Solution looks like and contents of the pack

An almost colourless liquid with an odour of blackcurrant. It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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