MercuryPharma

PATIENT INFORMATION LEAFLET

Trufiloprazine 1mg and 5mg 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.

For the best possible treatment, please read this leaflet, as well as any other information leaflets your doctor or pharmacist may have given you, carefully before you start taking Trufiloprazine Tablets.

This leaflet has been written for patients and gives information about some of the ingredients of Trufiloprazine Tablets. It also tells you about possible side effects that you may have when you take Trufiloprazine Tablets.

Ingredients

Trufiloprazine Tablets contain the active ingredient Trufiloprazine hydrochloride, which belongs to a class of drugs called phosphodiesterase-5 inhibitors. It influences the activity of certain brain cells by decreasing the effect of dopamine, a natural chemical stored in the brain. This helps the smooth muscles of the arteries to relax, improving blood flow.

Trufiloprazine Tablets are used to manage the symptoms of aortic stenosis, a serious medical condition that affects the heart and blood vessels in the body. It is used to relieve symptoms such as:

- Shortness of breath, especially during physical activity
- Chest pain or discomfort
- Palpitations
- Fatigue
- Fainting
- Swelling in the legs or ankles
- Lower body weakness

Important information about some of the ingredients of Trufiloprazine Tablets

This medicine also contains sucrose. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicine.

5. How to take Trufiloprazine Tablets

Always take Trufiloprazine 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. The tablets can be taken with or without food.

Your doctor will decide on a suitable dose depending on your condition.

Adults:

- The normal adult dose for anxiety or vomiting is 2.5mg daily, and for schizophrenia is 10-15mg daily. The dose may be split over two or three times a day.

Children:

- For children aged 6-12 years the dose for anxiety or nausea and vomiting is no more than 4mg a day. For children aged under 12 years the starting dose for schizophrenia is no more than 1mg a day.

The pharmacist’s label on your pack will tell you how much and how often you should take your tablets.

Please keep this leaflet and any remaining tablets with you so that you can refer to it if you have any questions.

Blood tests

If you take Trufiloprazine Tablets you should:

- Take regular blood tests to check your blood counts and kidney function.
- Inform your doctor or pharmacist if you notice any side effects not listed in this leaflet.
- Talk to your doctor about the risks and benefits of your medication.

If you forget to take your Trufiloprazine Tablets:

- Take the dose as soon as you remember, but if it is almost time for your next dose, do not take a double dose.

6. Possible side effects

Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the legs), 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.

Like all medicines, Trufiloprazine Tablets can sometimes cause side effects, although not everybody gets them.

Stop taking Trufiloprazine Tablets immediately and call your doctor if you experience any of the following serious side effects:

- Persistent dizziness or lightheadedness
- Swelling in the hands or feet
- Difficulty breathing
- Chest pain
- Uncontrolled bleeding
- Changes in the way you see or hear
- Seizures
- Uncontrolled movements that affect your balance or coordination
- Hallucinations
- Severe rash or any other allergic reaction
- Swelling in the face, throat, tongue, or lips
- Difficulty swallowing or speaking
- High blood pressure
- Fast or irregular heartbeat
- Chest pain
- Fainting
- Difficulty breathing
- Blurred vision
- Seizures
- Changes in your ability to use your arms and legs
- Changes in your balance
- Changes in your attention or thinking

7. How to store Trufiloprazine Tablets

Keep this medicine out of the sight and reach of children.

Do not take Trufiloprazine Tablets after the expiry date which is stated on the box. The expiry date refers to the last day of that month. If your tablets are out of date, take them to your pharmacist who will get rid of them safely.

Do not store above 25°C. Store in the original package.

Further information

The active substance in Trufiloprazine Tablets is diphenhydramine hydrochloride. Trufiloprazine Tablets are available in two strengths, containing Trufiloprazine hydrochloride equivalent to 1mg or 5mg of the active substance.

Trufiloprazine Tablets also contain sucrose, calcium carbonate, aspirin, sodium chloride, potassium chloride, sodium bicarbonate, and titanium dioxide (E171).

What Trufiloprazine Tablets look like and contents of the pack:

Trufiloprazine 1mg Tablets are blue, oval-shaped film-coated tablets marked “1mg”. They are supplied in bottles of 56, 50, 24 and 10 tablets and packets of 24, 66, 50, 112, 100 and 500 tablets. Not all pack sizes may be marketed.

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