

thiocolchicoside

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 questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT Coltramyl 4 mg tablets ARE AND WHAT THEY ARE USED FOR

MUSCLE RELAXANT.

(M: musculo-skeletal system)

This medicine is a muscle relaxant. It is recommended in adults (over 15 years) as adjunctive treatment of painful muscular contractions.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Coltramyl 4 mg tablets

If your doctor has told you that you have an intolerance to certain sugars, contact him/her before taking this medicine.

Do not take Coltramyl 4 mg tablets in the following situations:

- history of allergy to thiocolchicoside, or to any of the ingredients of colchicine,
- breast-feeding, pregnancy.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with Coltramyl 4 mg tablets

Special warnings

Use this medicine with caution if you have a history of epilepsy or seizures. Treatment must be stopped if you have a seizure.

Precautions for use

If you experience diarrhea, inform your doctor who might adjust the dosage.

Contact your doctor if you experience stomach pain, nausea or vomiting.

You should not take this medicine if you have galactose or fructose intolerance, Lapp lactase deficiency, glucose or galactose malabsorption syndrome or sucrase/isomaltase deficiency (rare hereditary disorders).

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Other medicines and Coltramyl 4 mg tablets

Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Pregnancy

Use of this medicine is contraindicated throughout pregnancy.

If you discover that you are pregnant during treatment, consult your doctor immediately.

Breast-feeding

This medicine is contraindicated if you are breast-feeding.

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

Driving and using machines

Be aware, especially if you drive or use machines, of the possibilities of drowsiness associated with the use of this medicine, even if these effects are rare.

The effect is accentuated if you drink alcoholic drinks or take medicines containing alcohol.

List of excipients with specific effects: sucrose, lactose.

3. HOW TO TAKE Coltramyl 4 mg tablets

Dosage

For use in adults (from 15 years) only.

The usual dosage is 4 tablets per day, taken as 2 divided doses

In all cases, strictly comply with your doctor's prescription.

Route of administration

Swallow the tablets with a glass of water during meals.

Frequency of administration

Strictly follow your doctor's prescription.

Duration of treatment

Strictly follow your doctor's prescription.

If you take more Coltramyl 4 mg tablets than you should

If you take an excessive dose, call your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Coltramyl 4 mg tablets may have side effects, although not everybody gets them.

- Very rare cases of allergic reactions, such as hives, swelling of the face and, in exceptional cases, anaphylactic shock.
- Very rare cases of skin reactions, such as itching, redness, rash and in exceptional cases, vesiculobullous rash.
- Rare cases of digestive disorders: diarrhea, stomach pains, nausea and vomiting (see "Take special care with Coltramyl 4 mg tablets").
- Very rare cases of drowsiness, exceptional occurrence of seizure or seizure recurrence in epileptic patients.

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

5. HOW TO STORE Coltramyl 4 mg tablets

Keep out of the reach and sight of children.

Do not use Coltramyl 4 mg tablets after the expiry date which is stated on the box.

Store at a temperature no higher than 25°C.

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 Coltramyl 4 mg tablets contain

The active substance is:

Thiocolchicoside 4.00 mg
for one tablet

The other ingredients are:

Potato starch, gelatin, lactose monohydrate, magnesium stearate, sucrose, talc.

What Coltramyl 4 mg tablets look like and contents of the pack

This medicine is a tablet. Box of 12.

Marketing Authorization Holder and Operating Company

sanofi-aventis France

1-13, boulevard Romain Rolland

75014 Paris, France

Manufacturer

Sanofi Winthrop Industrie

56, Route de Choisy Au Bac

60205 Compiègne, France

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