

Myolastan® 50 mg

tetrazepam

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

In this leaflet:

1. What Myolastan 50 mg scored film-coated tablets are and what they are used for
2. Before you take Myolastan 50 mg scored film-coated tablets
3. How to take Myolastan 50 mg scored film-coated tablets
4. Possible side effects
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1. WHAT Myolastan 50 mg scored film-coated tablets ARE AND WHAT THEY ARE USED FOR
OTHER CENTRALLY-ACTING AGENTS

This drug belongs to the benzodiazepine class.
This medicine is a muscle relaxant. It is used to treat adults (over 15 years of age) to reduce muscle spasms.

2. BEFORE YOU TAKE Myolastan 50 mg scored film-coated tablets

Never take Myolastan 50 mg scored film-coated tablets if you have:

- an allergy to this class of drugs or to one of the ingredients,
- severe respiratory failure,
- sleep apnea syndrome (*pauses in your breathing when you sleep*),
- severe liver failure,
- myasthenia (*disease involving excessive muscle fatigue*).

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

Take special care with Myolastan 50 mg scored film-coated tablets:

Special warnings

If a decrease in effectiveness occurs during repeated use of the drug, do not increase the dose.

Risk of **addiction**: this drug can, especially if used for a long time, cause a state of physical and mental addiction. Various factors seem to promote this:

- duration of treatment,
- dose,
- history of other addictions, to drugs or other substances, including alcohol.

You could become addicted to this medicine even if you have no risk factors.

For more information, ask your doctor or pharmacist.

Suddenly stopping treatment with this medicine can cause a withdrawal syndrome. This involves the occurrence, within a few hours or days, of symptoms such as significant anxiety, insomnia and muscle pain. However, agitation, irritability, headaches, numbness or tingling in the hands and feet, abnormal sensitivity to noise, light or physical contact, among other things, can also occur.

The method for stopping this treatment should be discussed with your doctor.

A very **gradual** decreasing of doses and longer intervals between doses are the best way to prevent this withdrawal syndrome. The longer the treatment period, the longer the treatment stopping phase should be.

Despite this gradual decreasing of the dose, a **rebound** effect that is not serious may occur, with **temporary** recurrence of the symptoms that originally required treatment.

Memory problems and psychomotor function disorders may also occur during the hours following treatment with the medicine.

In some subjects, this medicine may cause reactions that are opposite to the intended effects: insomnia, nightmares, agitation, nervousness, euphoria or irritability, tension, changes in consciousness or even potentially dangerous behavior (aggression or towards yourself or others, behavioral disturbances and automatic acts).

If one or more of these reactions occur, contact your doctor as soon as possible.

Benzodiazepines and related substances should be used with caution in elderly subjects because of the risk of drowsiness and/or muscle-relaxing effects that may promote falls, with implications that are often serious in this population.

Precautions for use

Taking this medicine requires increased medical supervision, particularly if you have kidney failure, chronic liver disease, alcoholism or respiratory failure.

You should not take this medication if you have depression that is untreated.

You are strongly advised against consuming alcohol or products containing alcohol while taking this treatment.

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

Taking or using other medicines

If you are currently taking or have recently taken another medicine, even one obtained without a prescription, inform your doctor or pharmacist.

In particular, you should avoid taking any medicine that may contain alcohol (see Section "Precautions for use").

It must be taken into account that many drugs or substances can have additive depressant effects on the central nervous system and contribute to a decrease in alertness. These drugs include morphine derivatives (analgesics, antitussives and replacement therapies), neuroleptics, barbiturates, benzodiazepines, non-benzodiazepine anxiolytics (such as meprobamate), hypnotics, sedative antidepressants (amitriptyline, doxepin, mianserin, mirtazapine, trimipramine), sedative H1 antihistamines, centrally-acting antihypertensives, baclofen and thalidomide.

Pregnancy and breast-feeding

Pregnancy

Treatment with this medicine should be avoided, as far as possible, during the first three months of pregnancy.

If the medicine has to be prescribed up until delivery, medical monitoring of the newborn baby is necessary.

Breast-feeding

This medicine passes into breast milk. Breast-feeding is therefore not recommended. Ask your doctor or pharmacist for advice before taking any medicine.

Driving vehicles or using machines

Please be aware that taking this drug may cause drowsiness and decreased alertness. Taking the drug along with other sedative or sleep medication, and of course with alcohol, is not recommended if you drive or use machines.

If you are not getting enough sleep, there is an even greater risk of decreased alertness.

3. HOW TO TAKE Myolastan 50 mg scored film-coated tablets

Dosage

For use in adults only (from 15 years).

Dosage *varies from one person to another*. Only your doctor can determine the correct dosage.

In all cases, follow your treating doctor's prescription.

Method of administration

Oral use.

Swallow the tablets whole with some water.

Duration of treatment

Treatment usually lasts a few days.

If you take more Myolastan 50 mg scored film-coated tablets than you should:

Immediately consult your doctor or pharmacist.

If you forget to take Myolastan 50 mg scored film-coated tablets:

Take the next dose at the usual time. Do not take a double dose to make up for the dose you forgot to take.

If you stop taking Myolastan 50 mg scored film-coated tablets:

Withdrawal and rebound effects may occur (see Section "Special warnings").

4. POSSIBLE SIDE EFFECTS

Like all medicines, **Myolastan 50 mg scored film-coated tablets** may cause side effects, although not all patients get them.

The side effects are related to the dose taken and individual patient sensitivity.

Psychiatric and nervous system effects (see Section "Take special care with Myolastan 50 mg scored film-coated tablets")

- memory disorders (forgetfulness), which may occur at therapeutic doses. The risk increases proportionally to the dose,
- behavioral disturbances, changes in consciousness, irritability, aggressiveness, agitation,
- physical and psychological addiction, even at therapeutic doses, with withdrawal or rebound effects on stopping treatment,
- feeling of drunkenness, headaches, difficulty in coordinating certain movements,
- confusion, decreased alertness or even drowsiness (particularly in elderly patients), insomnia, nightmares, tension,
- changes in libido.

Skin effects

- rash, itching, eczema, erythema multiforme,
- detaching of skin that can rapidly and very seriously extend over the entire body, fever, erosion in the mouth or on the genitals (Stevens-Johnson and Lyell's syndromes) requiring **urgent** medical attention.

Allergic effects

- allergic reactions such as hives and angioedema (sudden swelling of the face and neck) which may sometimes be severe and can cause sudden fainting and a drop in blood pressure.

Eye effects

- double vision.

Other effects

- muscle weakness, fatigue.

If you notice any side effects not mentioned in this leaflet, or if any of the side effects become serious, please inform your doctor or pharmacist.

5. HOW TO STORE Myolastan 50 mg scored film-coated tablets

Keep out of the reach and sight of children.

Do not take **Myolastan 50 mg scored film-coated tablets** after the expiry date indicated on the box.

The expiry date is the last day of the month indicated.

Store at a temperature no higher than 25°C.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist what to do with unused medicinal products. This will help protect the environment.

6. FURTHER INFORMATION

What do Myolastan 50 mg scored film-coated tablets contain?

The active substance is:50 mg
Tetrazepam For one scored film-coated tablet.

The other ingredients are:

Core: copovidone, magnesium stearate, microcrystalline cellulose, pregelatinized starch.
Film-coating: Opadry OY-S-38931 (hypromellose, talc, titanium dioxide (E171), glycerol triacetate), glycerol triacetate.

What Myolastan 50 mg scored film-coated tablets are and contents of the outer packaging

This medicine is in scored film-coated tablet form. Box of 20.

Marketing Authorization Holder and Operating Company

sanofi-aventis France
1-13, boulevard Romain Rolland
75014 Paris - France

Manufacturer

SANOI-AVENTIS, SA
Ctra. C-35 – La Batlloria a Hostalrich, Km 63,09
17404 - Riells i Viabrea (Gerona) – Espagne / Spain
This leaflet was last approved in: January 2010.

THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.