

PACKAGE LEAFLET: INFORMATION FOR THE USER

AMYZOL 10 mg, 25 mg

Film-coated Tablets

AMITRIPTYLINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Amyzol Tablets are and what they are used for
2. What you need to know before you take Amyzol Tablets
3. How to take Amyzol Tablets
4. Possible side effects
5. How to store Amyzol Tablets

1. WHAT AMYZOL TABLETS ARE AND WHAT THEY ARE USED FOR

Amitriptyline belongs to a group of medicines called tricyclic antidepressant drugs. These medicines alter the levels of chemicals in the brain to relieve the symptoms of depression.

Amyzol Tablets are used in following conditions:

- to treat the symptoms of depression.
- for the relief of bed-wetting at night by children known as nocturnal enuresis in children aged 6 years and above when organic pathology has been excluded and no response has been achieved to all other non-drug and drug treatments.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMYZOL TABLETS

Do not take Amyzol Tablets and tell your doctor if you or your child (if they are the patients):

- are allergic (hypersensitive) to amitriptyline, other tricyclic antidepressants or any of the other ingredients of Amyzol Tablets.. Allergy is more common in people who are allergic to aspirin. An allergic reaction can include a rash, itching or shortness of breath.
- have heart disease such as irregular heartbeats, heart block or failure, coronary artery disease or have recently had a heart attack
- suffer from periods of increased and exaggerated behaviour (mania)
- have severe liver disease

- are taking monoamine oxidase inhibitors (MAOI) or you have taken MAOIs within the previous 14 days for depression
- you are breast-feeding
- you have a problem with your blood called porphyria.

If this medicine has been prescribed for a child under 6 years of age, tell your doctor as it may not be suitable for them.

Warnings and precautions

Before taking Amyzol Tablets, tell your doctor if you or your child (if they are the patient):

- have any blood disorders (you may bruise easily, frequently suffer from infections or be anaemic)
- have any psychiatric disorder (e.g. schizophrenia or manic depression)
- have liver or cardiovascular disease
- cannot pass urine or have an enlarged prostate gland
- have an overactive thyroid gland and are taking medicines to treat a thyroid disorder
- have a history of epilepsy
- you are being given electroconvulsive therapy (ECT)
- you have increased pressure in the eye (known as narrow-angle glaucoma)
- are due to have any surgery, including dental that involves an anaesthetic.

A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG) and heart rhythm disorders (rapid or irregular heart beat) have been reported with Amyzol Tablets. Tell your doctor if you:

- have slow heart rate,
- have or had a problem where your heart cannot pump the blood round your body as well as it should (a condition called heart failure),
- are taking any other medication that may cause heart problems, or
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.

Nightly bedwetting:

1. Should not be combined with anticholinergic medicines
2. ECG (electrocardiogram) should be performed before starting therapy with Amitriptyline
3. During initiation of treatment development of suicidal thoughts and behaviours in patients receiving treatment for depression combined with treatment of nightly bedwetting.

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

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Having operations and tests

Tell your doctor or dentist that you are taking amitriptyline if you are going to have an anaesthetic for an operation or dental treatment.

Other medicines and Amyzol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please inform your doctor if you are taking or have previously taken any of the following medicines:

- medicines to treat depression known as Monoamine Oxidase Inhibitors (MAOIs) such as phenelzine or you have taken MAOIs within the last 14 days
- other medicines used to treat depression, including the herbal remedy St John's Wort
- altretamine (to treat some types of cancer)
- apraclonidine and brimonidine (to treat glaucoma ; a condition characterised by increased intraocular pressure)
- baclofen (a muscle relaxant)
- disulfiram (to treat alcohol addiction)
- painkillers such as nefopam, tramadol, codeine, dihydrocodeine
- medicines to treat some heart conditions such as amiodarone, diltiazem, disopyramide, procainamide, propafenone, quinidine, sotalol, verapamil
- medicines to treat angina that you spray or dissolve under your tongue (e.g. glyceryl trinitrate "GTN", isosorbide dinitrate)
- rifampicin or linezolid (to treat infections)
- carbamazepine or phenobarbital (to treat epilepsy)
- terfenadine (to treat allergies or hay fever)
- methylphenidate (to treat attention deficit/hyperactivity disorder in children (ADHD))
- any medicines to treat high blood pressure such as guanethidine, debrisoquine, bethanidine or clonidine or diuretics ("water" tablets)
- medicines to treat some mental illnesses such as clozapine, pimozide, thioridazine chlorpromazine, haloperidol, prochlorperazine, sulpiride
- cimetidine (to treat ulcers)
- ethchlorvynol (to help you sleep)
- entacapone or selegiline (to treat Parkinson's disease)
- oral contraceptives ("the pill")
- sibutramine (to suppress appetite)
- sympathomimetic medicines such as adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (norepinephrine), phenylephrine and phenylpropanolamine (these may be present in many cough and cold remedies)
- ritonavir (to treat HIV)
- fluconazole (to treat fungal infections).
- Anticholinergic medicines such as atropine, benztropine, dicyclomine, doxylamine when combined with Amitriptyline for nightly bedwetting therapy in children or when used in elderly patients.

Amyzol Tablets with food, drink and alcohol

You are advised not to drink alcohol with this medicine

Pregnancy and Breast-feeding

Amyzol Tablets should not be taken in the first 3 months and last 3 months of pregnancy. If taken in the last three months, the newborn may have withdrawal symptoms. Do not take Amyzol Tablets if you are breast-feeding.

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

Driving and using machines

Amitriptyline may make you feel drowsy. If you experience this, do not drive or use machinery.

Amyzol Tablets contains Lactose monohydrate

Amyzol Tablets contain lactose monohydrate (milk sugar); If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE AMYZOL TABLETS

Always take Amyzol 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. To be taken orally.

You are advised not to drink alcohol with this medicine.

You may not notice any improvement in your symptoms for up to 4 weeks after starting treatment.

The usual dosage is as below:

Depression:

Adults

The usual dose is 50-75mg each day either in divided doses or as a single night time dose. Your doctor may increase this dose to a maximum of 150-200 mg a day. A maintenance dose of 50- 100mg at night should be given to lessen the chances of relapse.

Adolescents and elderly - 25-50mg a day either in divided doses or as a single night time dose. A maintenance dose of 25-50mg may be sufficient.

Older people and people with kidney problems

Your doctor will start you on a lower dose and gradually increase it as you may be more sensitive to the medicine.

Children:

Not recommended for treatment of depression in children, under 16 years of age.

Nightly bedwetting:

Children only (for no longer than 3 months, if repeated treatment required then a medical review should be conducted every 3 months) 11-16 years: 25-50 mg per day at night. 6-10 years: 10-20 mg per day at night.

Children less than 6 years - Not recommended.

If you take more Amyzol Tablets than you should

If you or the patient (or someone else) swallows a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include fast or irregular heartbeat, low blood pressure, dilated pupils, drowsiness, low body temperature, fits, coma, difficulty breathing, agitation, muscle rigidity, jerky movements, hot dry skin, dry mouth and tongue, difficulty passing water, intestinal blockage, uncontrolled movements, being sick or fever.

If you forget to take Amyzol Tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take another as soon as you remember and then your next dose at the usual time.

If you stop taking Amyzol Tablets

You may not notice any improvement for up to 4 weeks. Do not stop taking the medicine unless your doctor tells you to as you may experience withdrawal symptoms (see section 4). If you stop taking the medicine abruptly, you may get side effects such as headache that makes you feel sick and feeling weak.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking Amyzol Tablets and contact your doctor straight away if you have:

- an allergic reaction. Signs may include a skin rash, which may be itchy, sensitivity to the sun or sun lamps, puffy, swelling of your face, lips, throat or tongue, which may be severe causing shortness of breath, swelling, shock and collapse.
- a serious effect on your blood, such as low sodium levels. Signs may include fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises.

If you notice any of these, tell your doctor straight away.

Serious side effects: tell your doctor straight away

- If you feel more depressed, including thinking about suicide.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Effects on your blood: bone marrow depression or reduction in some blood cells (you may experience a sore throat, mouth ulcers and recurring infections, bleeding or bruising easily)

• *Effects on your hormones:*

disturbances in sexual function or sex drive, breast swelling in men and women, swelling of the testicles, production or over-production of breast milk, changes in blood sugar levels, increased appetite and weight gain. Inappropriate secretion of the hormone ADH (antidiuretic hormone), which may make you urinate more frequently.

• *Effects on your brain and central nervous system:*

dizziness, tiredness or sleepiness, weakness, headache, difficulty concentrating, confusion, difficulty sleeping, nightmares, slight hyperactivity, exaggerated behaviour, delusions, seeing things that are not there (hallucinations), anxiety, excitement, disorientation (not knowing where you are), restlessness, numbness or tingling or pins and needles (particularly in the hands and feet), lack of co-ordination, shaky movements, tremor, fits, unconsciousness, slow or slurred speech. Anticholinergic effects (dry mouth, fever, constipation, blurred or double vision, difficulty passing water (urine), dilation of the pupil of the eye, glaucoma and blockage of the small intestine)

• *Effects on your heart:*

feeling faint when getting up (postural hypotension), change in blood pressure, fast/racing heart, palpitations, heart attack, stroke, irregular or slow heart-beats and very low pressure.

A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG) (frequency common)

• *Effects on your stomach and intestines:*

feeling or being sick, diarrhoea, change in appetite, irritation and a nasty taste in your mouth, swollen saliva glands, abdominal pains, black tongue, dry mouth, fever, constipation, blockage of your small intestine.

- **Effects on your liver:**

hepatitis, including changes in liver function (as seen in blood tests), jaundice (yellowing of the skin and/or whites of the eyes)

- **Effects on your ears:**

Buzzing or ringing in the ears.

- **Effects on your eyesight:**

blurred or double vision, changes in eyesight.

- **General effects:**

headache, dizziness, weakness, tiredness, change in weight, drowsiness, increased sweating, hair loss, widely dilated pupils, difficulty passing water (urine).

- **Effects on the skin:**

skin rashes, skin rash due to sunlight.

- **Withdrawal symptoms:**

feeling sick, malaise and headache, dream and sleep disturbances, irritability and restlessness. Mania or hypomania (exaggerated mood and/or elation) may occur 2-7 days after stopping the tablets.

An increased risk of bone fractures has been observed in patients taking this type of medicines.

When used for children to treat bed wetting, the side effects are less frequent but may still happen. The most common reported effects amongst children are drowsiness, dry mouth, blurred eyesight, increased pressure in the eye, changes in eyesight, constipation, fever and difficulty in passing water (urine) changes in behaviour and "Anticholinergic effects" (as described above). There have also been rare reports of mild sweating and itching.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMYZOL TABLETS

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

Keep out of the sight and reach of children.

Do not use your tablets after the expiry date stated on the label or carton.

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.

This leaflet was last approved in 11/2015.