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Amitriptyline Hydrochloride (POM)
10, 25 & 50 mg Film-Coated Tablets
Leaflet Size : 140(W) x 620(L) mm
MPLLAMIXXXXTBCOMFPLXXX052V08_A

140 mm

620 mm

PHARMA CODE XXXX

Pharmacode Reading Direction

PACKAGE LEAFLET: INFORMATION FOR THE USER
Amitriptyline Hydrochloride 10 mg Film-Coated Tablets
Amitriptyline Hydrochloride 25 mg Film-Coated Tablets
Amitriptyline Hydrochloride 50 mg Film-Coated Tablets

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

1. WHAT AMITRIPTYLINE HYDROCHLORIDE TABLET IS AND WHAT IT IS USED FOR

Amitriptyline Hydrochloride Tablets belongs to a group of medicines known as tricyclic antidepressants.

This medicine is used to treat:
- Depression in adults (major depressive episodes)
- Neuropathic pain in adults
- Chronic tension type headache prophylaxis in adults
- Migraine prophylaxis in adults
- Bed-wetting at night in children aged 6 years and above, only when organic causes, such as spina bifida and related disorders, have been excluded and no response has been achieved with other treatments non-pharmacological or pharmacological, including muscle relaxants and desmopressin. This medicine should only be prescribed by doctors with expertise in treating patients with persistent bed-wetting.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMITRIPTYLINE HYDROCHLORIDE TABLETS

Do not take Amitriptyline Hydrochloride Tablets:
- if you are allergic to amitriptyline hydrochloride or any of the other ingredients of this medicine (listed in Section 6).
- if you recently have had a heart attack (myocardial infarction)
- if you have heart problems such as disturbances in heart rhythm which are seen on an electrocardiogram (ECG), heart block, or coronary artery disease
- if you are taking medicines known as monoamine oxidase inhibitors (MAOIs)
- if you have taken MAOIs within the last 14 days
- if you have taken moclobemide the day before
- if you have a severe liver disease

If you are treated with Amitriptyline Hydrochloride Tablets, you have to stop taking this medicine and wait for 14 days before you start treatment with a MAOI.

This medicine should not be used for children below 6 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking Amitriptyline Hydrochloride Tablets.

Heart rhythm disorders and hypotension may occur if you receive a high dose of amitriptyline. This can also happen with the usual doses if you have a pre-existing heart disease.

"QT prolongation" (seen on the electrocardiogram, ECG) and heart rhythm disorders (fast or irregular heartbeat) related to the administration of Amitriptyline Hydrochloride Tablets have been reported. Tell your doctor if:
- note a slow heart rate;
- has or has had a problem in which the heart could not properly pump blood through the body (i.e., a condition called "heart failure");
- taking any other medications that can cause heart problems; or
- have a problem that has reduced your potassium or magnesium level or a high level of potassium in your blood.
- have a surgery planned as it might be necessary to stop the treatment with amitriptyline before you are given anaesthetics. In the case of acute surgery, the anaesthetist should be informed about the treatment of amitriptyline.
- have an over active thyroid gland or receive thyroid medication.
- The use of Buprenorphine together with Amitriptyline tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Amitriptyline Hydrochloride Tablets").
- Take special care with Amitriptyline Hydrochloride: Serious cutaneous reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Amitriptyline Hydrochloride treatment. Stop using AmitriptylineHydrochloride and seek medical attention immediately if you notice any of the symptoms related to these serious cutaneous reactions described in section 4.

Thoughts of Suicide and Worsening of Your Depression or Anxiety Disorder
If you are depressed and / or have an anxiety disorder, you may sometimes have thoughts of hurting yourself or committing suicide. This can increase at the beginning of taking antidepressants, because all these medicines take a while to take effect, usually about two weeks but sometimes can be longer.

This is more likely to happen to you:
- If you have previously had thoughts of suicide or hurt yourself.
- If you are a young adult. There is information from clinical trials showing that there is an increased risk of suicidal behavior in adults under age 25 with psychiatric illnesses being treated with antidepressants.

If you have thoughts of hurting yourself or committing suicide at any time, **contact your doctor or go to the hospital immediately.**

It may be helpful for you to explain to a family member or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You can also ask them to tell you if they think their depression or anxiety is getting worse, or if they are worried about changes in their behavior.

Episodes of mania
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity. In such cases, it is important to contact your doctor who probably will change your medication.

Tell your doctor if you have, or have had in the past, any medical problems, especially if you have
- narrow angle glaucoma (loss of vision due to abnormally high pressure in the eye)
- epilepsy, a history of convulsions or fits
- difficulty in passing urine
- enlarged prostate
- thyroid disease
- bipolar disorder
- schizophrenia
- severe liver disease
- severe heart disease
- pylorus stenosis (narrowing of the gastric outlet) and paralytic ileus (blocked intestine)
- diabetes as you might need and adjustment of your antidiabetic medicine.

If you use antidepressants such as SSRIs, your doctor might consider changing the dose of your medicine (see also section 2 Other medicines and Amitriptyline Hydrochloride Tablets and section 3).

Elderly are more likely to suffer from certain side effects, such as dizziness when you stand up due to low blood pressure (see also section 4 Possible side effects).

Children and adolescents
Depression, neuropathic pain, chronic tension type headache and migraine prophylaxis
Do not give this medicine to children and adolescents aged below 18 years for these treatments as safety and efficacy have not been established in this age group.

Bed-wetting at night
- An ECG should be performed prior to initiating therapy with amitriptyline to exclude long QT syndrome
- This medicines should not be taking at the same time as an anticholinergic drug (see also section 2 Other medicines and Amitriptyline Hydrochloride Tablets)
- Suicidal thoughts and behaviours may also develop during early treatment with antidepressants for disorders other than depression; the same precautions observed when treating patients with depression should therefore be followed when treating patients with enuresis

Other medicines and Amitriptyline Hydrochloride Tablets
Some medicines may affect the action of other medicines and this can sometimes cause serious side effects.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:
- monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson's disease). These should not be taken at the same time as Amitriptyline Hydrochloride Tablets (see section 2 Do not take Amitriptyline Hydrochloride Tablets)
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (these may be present in cough or cold medicine, and in some anaesthetics)
- medicine to treat high blood pressure for example calcium-channel blockers (e.g. diltiazem and verapamil), guanethidine, betanidine, clonidine reserpine and methyldopa
- anticholinergic drugs such as certain medicines to treat Parkinson's disease and gastrointerstinal disorders (e.g. atropine, hyoscyamine)
- thioridazine (used to treat schizophrenia)
- tramadol (painkiller)
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole)
- sedatives (e.g. babiturates)
- antidepressants (e.g SSRIs (fluoxetine, paroxetine, fluvoxamine), and bupropion)
- medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics)
- cimetidine (used to treat stomach ulcers)
- methylphenidate (used to treat ADHD)
- ritonavir (used to treat HIV)
- oral contraceptives
- rifampicin (to treat infections)
- phenytoin and carbamazepine (used to treat epilepsy)
- St. John's Wort (hypericum perforatum) – a herbal remedy used for depression
- thyroid medication
- Valproic acid
- Buprenorphine/opioids-These medicines may interact with Amitriptyline and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

You should also tell your doctor if you take or have recently taken medicine that may affect the heart's rhythm. e.g.:
- medicines to treat irregular heartbeats (e.g. quinidine and sotalol)
- astemizole and terfenadine (used to treat allergies and hayfever)
- medicines used to treat some mental illnesses (e.g. pimozide and sertindole)
- cisapride (used to treat certain types of indigestion)
- halofantrine (used to treat malaria)
- methadone (used to treat pain and for detoxification)
- diuretics ("water tablets" e.g. furosemide)

If you are going to have an operation and receive general or local anaesthetics, you should tell your doctor that you are taking this medicine.

Likewise, you should tell your dentist that you take this medicine if you are to receive a local anaesthetic.

Amitriptyline Hydrochloride Tablets with alcohol
As with all medicines of this type that act on the central nervous system, it is necessary to avoid alcohol while you are taking this medicine as it might increase the sedative effect.

Pregnancy, breast-feeding and fertility
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.

Amitriptyline is not recommended during pregnancy unless your doctor considers it clearly necessary and only after careful consideration of the benefit and risk. If you have taken this medicine during the last part of the pregnancy, the newborn may have withdrawal symptoms such as irritability, increased muscle tension, tremor, irregular breathing, poor drinking, loud crying, urinary retention, and constipation.

Your doctor will advise you whether to start/ continue/stop breast-feeding, or stop using this medicine taking into account the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines
This medicine may cause drowsiness and dizziness, especially in the beginning of the treatment. Do not drive or work with tools or machinery if you are affected.

Amitriptyline Tablets contains Lactose
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 AMITRIPTYLINE HYDROCHLORIDE TABLETS

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

Not all dosage schemes can be achieved with all the pharmaceutical forms/strengths. The appropriate formulation/strength should be selected for the starting doses and any subsequent dose increases.

Depression
Adults
The recommended initial dose is 25 mg two times daily.

Depending on your response to the medicine, your doctor may gradually increase the dose to 150 mg per day divided in two doses.

Elderly (above 65 years of age) and patients with cardiovascular disease
The recommended initial dose is 10 mg – 25 mg daily.
Depending on your response to the medicine, your doctor may gradually increase the dose to a total daily dose of 100 mg divided in two doses. If you receive doses in the range of 100 mg – 150 mg, your doctor may need to do more frequent follow-up with you.

Use in children and adolescents
This medicine should not be given to children or adolescents for treatment of depression. For further information please see section 2.

Neuropathic pain, chronic tension type headache and migraine prophylaxis
Your doctor will adjust the medication according to your symptoms and your response to the treatment.

Adults
The recommended initial dose is 10 mg - 25 mg in the evening.

The recommended daily dose is 25 mg - 75 mg.

Depending on your response to the medication, your doctor may gradually increase the dose. You are given a dose of more than 100 mg daily; your doctor may have to visit most frequent monitoring. Your doctor will tell you if you should take the dose once a day or divide it into two doses.

Elderly (above 65 years of age) and patients with cardiovascular disease
The recommended initial dose is 10 mg – 25 mg in the evening.

Depending on your response to the medicine, your doctor may gradually increase the dose. If you receive doses above 75 mg daily, your doctor may need to do more frequent follow-up with you.

Use in children and adolescents
This medicine should not be given to children or adolescents for treatments of neuropathic pain, chronic tension type headache prophylaxis and migraine prophylaxis.
For further information please see section 2.

Bed-wetting at night
Use in children and adolescents
The recommended doses for children:
- aged below 6 years: see section 2 Do not take Amitriptyline Hydrochloride Tablets
- aged 6 to 10 years: 10 mg – 20 mg daily. A suitable dosage form should be used for this age group.
- aged 11 years and above: 25 mg – 50 mg.

The dose should be increased gradually.

Take this medicine 1-1½ hours before bedtime.

Before starting treatment, your doctor will conduct an ECG of your heart to check for sign of unusual heartbeat.

Your doctor will re-evaluate your treatment after 3 months and if needed perform a new ECG.

Do not stop the treatment without consulting your doctor first.

Patients with special risks
Patients with liver diseases or people known as "poor metabolisers" usually receive lower doses.
Your doctor may take blood samples to determine the level of amitriptyline in the blood (see also section 2).

How and when to take Amitriptyline Hydrochloride Tablet
This medicine can be taken with or without food. Swallow the tablets with a drink of water. Do not chew them.

Duration of treatment
Do not change the dose of the medicine or stop taking the medicine without consulting your doctor first.
Depression
As with other medicines for the treatment of depression it may take a few weeks before you feel any improvement.

In treating depression the duration of treatment is individual, and is usually at least 6 months. The duration of treatment is decided by your doctor.

Continue to take this medicine for as long as your doctor recommends.

The underlying illness may persist for a long time. If you stop your treatment too soon, your symptoms may return.

Neuropathic pain, chronic tension type headache and migraine prophylaxis. It might take a few weeks before your feel any improvement of your pain.

Talk to your doctor about the duration of your treatment and continue to take this medicine for as long as your doctor recommends.

Bed-wetting at night
Your doctor will evaluate if the treatment should be continued after 3 months.

If you take more Amitriptyline Hydrochloride Tablets than you should
If you take more than the prescribed dose, contact your doctor immediately so that you can be given prompt medical attention. Do this even if there are no signs of discomfort or poisoning. Take the container of this medicine with you if you go to a doctor or hospital.

Symptoms of overdose include:
- dilated pupils
- fast or irregular heartbeats
- difficulties passing water
- dry mouth and tongue
- intestinal blockage
- fits
- fever
- confusion
- hallucinations
- uncontrolled movements
- low blood pressure, weak pulse, pallor
- agitation
- difficulty breathing
- blue discolouration of the skin
- decreased heart rate
- drowsiness
- loss of consciousness
- coma
- various cardiac symptoms such as heart block, heart failure, hypotension, cardiogenic shock, metabolic acidosis, hypokalemia.

If you forget to take Amitriptyline Hydrochloride Tablets
Take Amitriptyline Hydrochloride Tablets as prescribed.
However, if you forget to take a dose, do not take an extra dose. Just take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amitriptyline Hydrochloride Tablets
Your doctor will decide when and how to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped abruptly (e.g. headache, feeling unwell, sleeplessness and irritability).

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

4. POSSIBLE SIDE EFFECTS

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

If you get any of the following symptoms you should see your doctor immediately:

- Signs of a severe allergic reaction (anaphylaxis) such as swelling of your tongue or face, or difficulty breathing.

- Attacks of intermittent blurring of vision, rainbow vision, and eye pain. You should immediately have an eye examination before the treatment with this medicine can be continued. This condition may be signs of acute glaucoma. Very rare side effect, may affect up to 1 in 10,000 people.

- A heart problem called "prolonged QT interval" (which is shown on your electrocardiogram, ECG). Common side effect, may affect up to 1 in 10 people.

- Bad constipation, a swollen stomach, fever and vomiting.
These symptoms may be due to parts of the intestine becoming paralysed. Rare side effect, may affect up to 1 in 1,000 people.

- Any yellowing of the skin and the white in the eyes (jaundice). Your liver may be affected. Rare side effect, may affect up to 1 in 1,000 people.

- Bruising, bleeding, pallor or persistent sore throat and fever. These symptoms can be the first signs that your blood or bone marrow may be affected. Effects on the blood could be a decrease in the number of red cells (which carry oxygen around the body), white cells (which help to fight infection) and platelets (which help with clotting). Rare side effect, may affect up to 1 in 1,000 people.

- Suicidal thoughts or behaviour. Rare side effect, may affect up to 1 in 1,000 people.

Side effects listed below have been reported in the following frequencies:

Very common: may affect more than 1 in 10 people
- sleepiness/drowsiness
- shakiness of hands or other body parts
- dizziness
- headache
- irregular, hard, or rapid heartbeat
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- dry mouth
- constipation
- nausea
- excessive sweating
- weight gain
- slurred or slow speech
- aggression
- nasal congestion

Common: may affect up to 1 in 10 people
- confusion
- sexual disturbances (decreased sex-drive, problems with erection)
- disturbance in attention
- changes in taste
- numbness or tingling in the arms or legs
- disturbed coordination
- dilated pupils
- heart block
- fatigue
- low sodium concentration in the blood
- agitation
- urination disorders
- feeling thirsty

Uncommon: may affect up to 1 in 100 people
- excitement, anxiety, difficulties sleeping, nightmares
- convulsions
- tinnitus
- increased blood pressure
- diarrhoea, vomiting
- skin rash, nettle rash (urticarial), swelling of the face and tongue
- difficulties passing urine
- increased production of breast milk or breast milk outflow without breast feeding
- increased pressure in the eye ball
- collapse conditions
- worsening of cardiac failure
- liver function impairment (e.g. cholestatic liver disease).

Rare: may affect up to 1 in 1,000 people
- decreased appetite
- delirium (especially in elderly patients), hallucinations (especially in patients with schizophrenia),
- abnormality in the heart's rhythm, or heartbeat pattern
- swelling of the salivary glands
- hair loss
- increased sensitivity to sunlight
- breast enlargement in men
- fever
- weight loss
- abnormal results of liver function tests.

Very rare: may affect up to 1 in 10,000 people
- heart muscle disease
- feeling of inner restlessness and a compelling need to be in constant motion
- disorder of the peripheral nerves
- acute increase of pressure in the eye
- particular forms of abnormal heart rhythm (so called torsades de pointes)
- allergic inflammation of the lung alveoli and of the lung tissue

Not known: frequency cannot be estimated from the available data
- absent sensation of appetite
- elevation or lowering of blood sugar levels
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- hepatitis
- hot flush
- dry eyes.

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

Stop using Amitriptyline Hydrochloride and seek medical attention immediately if you notice any of the following symptoms: Widespread rash, high body temperature and enlarged lymph nodes (DRESS or drug hypersensitivity syndrome).

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMITRIPTYLINE HYDROCHLORIDE TABLETS

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

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store below 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 Amitriptyline Hydrochloride Tablets contains:
- Each film-coated tablet contains 10 mg of Amitriptyline hydrochloride.
- Each film-coated tablet contains 25 mg of Amitriptyline hydrochloride.
- Each film-coated tablet contains 50 mg of Amitriptyline hydrochloride.

The other ingredients are:
Amitriptyline Hydrochloride 10 mg Film-coated Tablets:
Microcrystalline cellulose, lactose monohydrate, pregelatinised starch, colloidal anhydrous silica, magnesium stearate, opadry Y-1-7000 H White which contains hypromellose (E464), titanium dioxide (E171) and macrogol (E1521).

Amitriptyline Hydrochloride 25 mg Film-coated Tablets:
Microcrystalline cellulose, lactose monohydrate, pregelatinised starch, colloidal anhydrous silica, magnesium stearate, opadry AMB II 88A570008 TAN which contains polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171), iron oxide yellow (E172), GMCC type 1, sodium lauryl sulfate and iron oxide red (E172).

Amitriptyline Hydrochloride 50 mg Film-coated Tablets:
Microcrystalline cellulose, lactose monohydrate, pregelatinised starch, colloidal anhydrous silica, magnesium stearate, opadry brown 20B565005 which contains hypromellose (E464), hydroxypropyl cellulose (E463), polyethylene glycol (E1521), titanium dioxide (E171), iron oxide red (E172) and iron oxide yellow (E172).

What Amitriptyline Hydrochloride Tablets looks like and contents of the pack
Amitriptyline Hydrochloride 10 mg Film-coated Tablets are White,, round, biconvex film coated tablets debossed with "FL14" on one side and plain on other side.

Amitriptyline Hydrochloride 25 mg Film-coated Tablets are Yellow, round, biconvex film coated tablets debossed with "FL15" on one side and plain on other side.

Amitriptyline Hydrochloride 50 mg Film-coated Tablets are Brown, round, biconvex film coated tablets debossed with "FL21" on one side and plain on other side.

Amitriptyline Hydrochloride Film-Coated Tablets are available in blisters of Aluminium-PVC/PVDC containing packs of 28's, 30's, 56's, 60's, 84's, 90's, 112's and 120's along with leaflet inside. Not all pack sizes may be marketed.

Amitriptyline Hydrochloride Film-Coated Tablets are available in white opaque HDPE bottle with white polypropylene cap containing packs of 30, 100, 500 and 1000 tablets.
Not all pack sizes may be marketed.

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Colour Scheme : Black	**Ref. Artwork : MPLLAMIXXXXTBCOMFPLXXX052V08**

Prepared By	Reviewed & Checked By			Approved by	
Artwork	**Pkg. Development**	**Marketing**	**Regulatory**	**CQA**	**MAH**
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