Composition fonts size: 9 pt.

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.

effects not listed in this leaflet. See section 4.

• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side

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

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

be prescribed by doctors with expertise in

treating patients with persistent bed-wetting.

Do not take Amitriptyline Hydrochloride 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

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

Hydrochloride Tablets'). Thoughts of Suicide and Worsening of Your Depression or Anxiety Disorder

(see "Other medicines and Amitriptyline

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 ometimes can be longer.

This is more likely to happen to you:

If you have previously had thoughts of suicide or hurt vourself. 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

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

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 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

Date:

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 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 tranyleypromine (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

Hydrochloride Tablets) adrenaline, ephedrine, isoprenaline. noradrenaline, phenylephrine and phenylpropanolamine (these may be present in cough or cold medicine, and in some anaesthetics)

section 2 Do not take Amitriptyline

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 Parkinsons 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 havfever) 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

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

general or local anaesthetics, you should tell your

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 breastfeeding for your child and the benefit of therapy

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

Depression

Date:

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

dailv. Depending on your response to the medicine, you 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

Date:

140 mm

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

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 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 months and if needed perform a new ECG.

Do not stop the treatment without consulting your

Patients with special risks Patients with liver diseases or people known as "poor metabolisers" usually receive lower Your doctor may take blood samples to determine

the level of amitriptyline in the blood (see also

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 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

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

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

Symptoms of overdose include: dilated pupils · difficulty breathing

doctor or hospital.

fast or irregular heartbeats • blue discolouration difficulties passing water of the skin dry mouth and tongue · decreased heart rate intestinal blockage drowsiness loss of fever consciousness

confusion coma hallucinations various cardiac uncontrolled symptoms such as movements heart block, heart low blood pressure, weak failure, hypotension pulse, pallor 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 If you stop taking Amitriptyline Hydrochloride

Your doctor will decide when and how to stop you 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: 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 is

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

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 dry mouth

Date:

shakiness of hands or constipation other body parts nausea dizziness headache excessive sweating weight gain irregular, hard, or rapid heartbeat slurred or dizziness when you stand slow speech up due to low blood pressure • aggression (orthostatic hypotension) • nasal conge nasal congestion

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

Uncommon: may affect up to 1 in 100 people excitement, anxiety, increased production of difficulties sleeping, breast milk or breast milk outflow without nightmares convulsions breast feeding tinnitus increased pressure in the eye ball increased blood collapse conditions pressure diarrhoea, vomiting worsening of cardiac

skin rash, nettle rash (urticarial), swelling · liver function of the face and tongue impairment difficulties passing (e.g. cholestatic liver Rare: may affect up to 1 in 1,000 people decreased appetite hair loss

delirium (especially in • increased sensitivity to

sunlight

hallucinations breast enlargement in (especially in patients men with schizophrenia), fever abnormality in the weight loss heart's rhythm, or • abnormal results of heartbeat pattern liver function tests. swelling of the salivary glands

elderly patients),

pressure in the eye

the available data

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

• absent sensation of appetite hypersensitivity · elevation or lowering of inflammation of blood sugar levels heart muscle paranoia p hepatitis

Not known: frequency cannot be estimated from

movement disorders hot flush (involuntary movements dry eyes. or decreased movements) An increased risk of bone fractures has been

observed in patients taking this type of medicines 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 distributed to the side effects. 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.

INFORMATION What Amitriptyline Hydrochloride Tablets contains:

6. CONTENTS OF THE PACK AND OTHER

Amitriptyline hydrochloride. Each film-coated tablet contains 25 mg of Amitriptyline hydrochloride. Each film-coated tablet contains 50 mg of Amitriptyline hydrochloride.

• Each film-coated tablet contains 10 mg of

The other ingredients are: Amitriptyline Hydrochloride 10 mg Film-coated 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 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 vellow (E172), GMCC type 1, sodium lauryl

sulfate and iron oxide red (E172). Amitriptyline Hydrochloride 50 mg Film-coated 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).

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 Amitriptyline Hydrochloride 25 mg Film-coated

What Amitriptyline Hydrochloride Tablets

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

Tablets are Yellow, round, biconvex film coated

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, 120's, 120'

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. Marketing Authorization Holder Flamingo Pharma (UK) Ltd. lst Floor, Kirkland House, 11-15 Peterborough Road Harrow, Middlesex, HA1 2AX,

United Kingdom.

PL 43461/0054 PL 43461/0055 PL 43461/0056

Date:

Flamingo Pharma (UK) Limited The Bloc, 38 Springfield Way, Anlaby, Hull, HU10 6RJ, This leaflet was last revised in 11/2022.

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Code: MPLLAMIXXXXTBCOMFPLXXX052V07 Customer / Livery : FPL UK **Colour Scheme :** Black Ref. Artwork: MPLLAMIXXXXTBCOMFPLXXX052V06 **Prepared By Reviewed & Checked By** Approved by MAH Artwork Pkg. Development Marketing Regulatory CQA Sign. Sign. Sign. Sign. Sign. Sign.

Date:

620 mm