

## CLEAN PATIENT INFORMATION LEAFLET FOR AMDERIP

### SCHEDULING STATUS

S5

#### **AMDERIP 10 / 25 / 50 (film-coated tablets)**

Amitriptyline hydrochloride

Contains sugar: Lactose monohydrate

#### **Read all of this leaflet carefully before you start taking AMDERIP**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AMDERIP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

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

#### **1. What AMDERIP is and what it is used for**

AMDERIP belongs to a group called tricyclic antidepressants and contains amitriptyline hydrochloride. AMDERIP is used to treat the symptoms of depression in patients 18 years and older.

## **2. What you need to know before you take AMDERIP**

### **Do not take AMDERIP:**

- If you are allergic (hypersensitive) to amitriptyline hydrochloride or any of the other ingredients of AMDERIP (listed in section 6),
- if you recently had a heart attack,
- if you have heart disease, heart failure or irregular heartbeats,
- if you are taking monoamine oxidase inhibitors (MAOIs) or have taken MAOIs within the last 14 days, such as selegiline,
- if you are taking linezolid which is an antibiotic,
- if you are taking medicines for the treatment high blood pressure, such as amlodipine, nifedipine,
- if you are pregnant, intend to become pregnant or if you are breastfeeding your baby,
- if the child is under the age of 18,
- if you have periods of increased or exaggerated behaviour (mania),
- if you have severe liver disease.

### **Warnings and precautions**

Special care should be taken with AMDERIP:

- If you experience dry mouth, constipation, difficulty urinating and blurred vision or vision problems, you should consult your doctor.
- If you have drowsiness, agitation, restlessness, difficulty sleeping (insomnia) and restlessness.
- If you have high blood pressure (hypertension) or a heart condition/disorder.
- If you have high blood sugar levels (diabetes).
- If you experience changes in your sex drive (libido), interference with sexual function, swelling of breasts in women, breast swelling in men (gynaecomastia) and flow of milk

from breast when not breastfeeding (galactorrhoea).

- If you have a psychiatric disorder (depression or mania).
- If you have thoughts of killing or harming yourself (suicidal tendencies).
- If you are planning or due to have a surgery that requires anaesthetic.
- If you drink alcohol.
- If you have a condition called porphyria.
- If you have a problem with your thyroid gland.
- If you have a liver condition/disorder.
- If you have and eye condition called glaucoma which is an increase in eye pressure.
- If you develop an allergic skin reaction (skin rash, itching, swelling of the face/tongue) after taking AMDERIP.
- If you suffer from fits or seizures (epilepsy).
- If you have problems passing urine (urinary retention).
- If you have an enlarged prostate.
- If you are having electroconvulsive therapy (ECT) which is procedure when electric currents are passed through the brain.
- If you develop low sodium levels in your blood you may feel the following symptoms: drowsiness, confusion or have fits/seizures.
- If you are older 65 years of age.
- If you are younger than 18 years of age as AMDERIP is not recommended.
- AMDERIP should at all times be kept out of reach of children as even small doses may be fatal to them.
- Drowsiness is often experienced at the start of AMDERIP therapy.

### **Lactose warning**

AMDERIP contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AMDERIP.

## **Other medicines and AMDERIP**

Always tell your healthcare provider if you are taking any other medicine (This includes all complementary or traditional medicines).

AMDERIP could interact with other medicines and the dosages of the medicines might have to be changed by your doctor as the amounts of AMDERIP or other medicines in your blood may be affected.

- Monoamine oxidase inhibitors (e.g. selegiline) which is used to treat depression.
- Medicines also used to treat depression (serotonin reuptake inhibitors such as fluoxetine or norepinephrine reuptake inhibitors such as reboxetine).
- Apraclonidine or brimonidine which is used to treat the eye disorder called glaucoma (increase in eye pressure).
- If you are planning or due to have a surgery that requires anaesthetic (medicine that reduces your feeling to pain).
- Medicines that are used to treat heart conditions/disorders such as amiodarone, disopyramide, procainamide, sotalol, propafenone, quinidine, isoprenaline.
- Rifampicin which is used to treat tuberculosis decreases the effect of AMDERIP.
- Antibiotics such as linezolid which is used to treat bacterial infections.
- Verapamil and diltiazem (calcium channel blockers), debrisoquine, bethanidine, guanethidine and clonidine which are medicines used to treat high blood pressure.
- Medicines such as adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (norepinephrine), phenylephrine or phenylpropanolamine which may be found in cough mixtures or cold remedies.
- Barbiturates which are medicines cause central nervous system depression, including medicines used to treat anxiety and sleeping disorders, such as phenobarbitone.
- Carbamazepine which is used to treat fits/ seizures (epilepsy).

- Opioid analgesics such as tramadol which is used to treat pain as there may be a possibility of increased drowsiness and sedation when taken with AMDERIP.
- Medicines used to treat fungal infections such as fluconazole.
- Disulfiram which is used to treat alcohol abuse.
- Antivirals such as ritonavir which is used to treat HIV infections, may increase the blood levels of amitriptyline which is found in AMDERIP.
- Antihistamines which are used to treat allergies.
- Methylphenidate which is used to treat attention-deficit disorder.
- Oral contraceptives may reduce the antidepressant effect of AMDERIP.
- Thyroid preparations used to treat thyroid gland disorders.
- Cimetidine which used to treat stomach ulcers and heartburn.
- Medicines used to treat Parkinson's disease.
- Medicines used to relax the muscles or treat muscle cramps such as baclofen.
- Diuretics (water tablets) such as furosemide used to treat high blood pressure.
- Nitrates which are a medicine used to treat angina (pain from not enough blood going to the heart).
- Medicines used to treat psychiatric disorders such as thioridazine or pimozide.
- St. John's Wort which is an herbal medicine used to treat depression.

### **AMDERIP with alcohol**

Amitriptyline found in AMDERIP may increase the effects of alcohol (such as drowsiness/sedation). It is therefore necessary to avoid alcohol while taking this medication.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

### **Driving and using machines**

When you start to take AMDERIP, you should not drive a motor vehicle, climb dangerous heights or operate dangerous machinery for at least several days. Impaired decision making can lead to accidents while doing these actions. AMDERIP may cause drowsiness, dizziness, blurred vision and may affect your [f] concentration. You should therefore not drive, operate machinery or perform tasks that need you to concentrate, until you are certain that AMDERIP does not affect your ability to do so.

Check with your doctor before taking this medicine as AMDERIP may affect the sugar levels in your blood.

### **3. How to take AMDERIP**

Do not share medicines prescribed for you with any other person.

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

The usual dose is:

Initially 75 mg to 150 mg daily in divided doses.

Maintenance dose is 50 mg to 100 mg daily in divided doses.

Your doctor will tell you how long your treatment with AMDERIP will last. If you have the impression that the effect of AMDERIP is too strong or too weak, tell your doctor or pharmacist.

### **If you take more AMDERIP than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have

taken.

You may experience an increase in side effects caused by AMDERIP such as drowsiness, restlessness, unsteady body movement, unconscious state (coma), stunned state in which it is difficult to get a response or the attention (stupor), changes in your normal heartbeat (cardiac dysrhythmias), fever, irregular heartbeats that you can feel (palpitations), low blood pressure (hypotension), fast heart rate (tachycardia), fits/seizures and difficulty breathing.

### **If you forget to take use AMDERIP**

If you forget to take a tablet, take the missed dose right away, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

### **If you stop taking using AMDERIP**

Do not stop taking AMDERIP or decrease the dose without checking with your doctor.

## **4. Possible side effects**

AMDERIP can have side effects.

Not all side effects reported for AMDERIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMDERIP, please consult your healthcare provider for advice.

If any of the following happens, stop taking AMDERIP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash or itching,
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to AMDERIP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Heart attack: symptoms may include pain or pressure in your chest, discomfort spreading to the back, arm, throat or jaw, heartburn or indigestion, shortness of breath, anxiety, weakness or rapid/irregular heartbeats.

- Stroke: symptoms may include sudden numbness (loss of feeling) or weakness of the face, arm or leg especially on one side of the body, confused state, trouble speaking or understanding speech, sudden trouble seeing in one or both eyes, sudden trouble walking, loss of balance or coordination, dizziness and sudden severe headache without a known cause.

Yellowing of skin and eyes (jaundice).

- Coma (state of unconsciousness).
- Feeling faint when getting up (postural hypotension), palpitations, fast/racing heart, increased blood pressure, slow or irregular heartbeats, and very low blood pressure.
- Bone marrow depression or a decrease in some blood cells. You may experience bleeding or bruising easily, recurring infections or mouth ulcers,
- Difficulty passing water (urine).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Drowsiness or sleepiness.
- Blurred vision, increased pressure in the eye or difficulty focusing when looking at an object (accommodation disturbances).
- Constipation.
- Dry mouth.

- Body temperature rises above normal (hyperthermia).

*Less frequent side effects:*

- Skin rash that looks like pale red itchy bumps (urticaria).
- Reaction of skin to sunlight.
- Inadequate secretion of ADH (antidiuretic hormone) causing you to urinate more often, changes in blood sugar level and blood sodium levels.
- Dizziness, headache, weakness, numbness or pain in hands or feet, pins and needles, lack of coordination, unsteady body movement (ataxia), tremors (shaking), fits, stiff or jerky movements of your face and body that you can't control.
- Enlarged (dilated) pupil of the eyes.
- Confusion, not knowing where you are (disorientation), agitation, feeling anxious, restlessness, difficulty sleeping, nightmares, unable to concentrate,
- Suicidal thoughts or behavior, changes in behavior.
- Difficulty speaking due to muscle weakness.
- Ringing sound in the ears.
- Diarrhoea, constipation, feeling sick (nausea), being sick (vomiting), swelling in the mouth, dry mouth, swelling of the parotid gland which produces saliva or spit, black tongue, stomach pain.
- Swelling of the liver (hepatitis).
- Temporary hair loss.
- Passing water (urine) more often.
- Breast swelling in men and women, flow of milk from breast when not breastfeeding, swelling of testicles, changes in sex drive.
- Feeling tired or weak.
- Increased sweating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AMDERIP.

### **5. How to store AMDERIP**

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package/container.

Do not store in a bathroom.

Do not use AMDERIP after the expiry date.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What AMDERIP 10 contains:**

The active substance is amitriptyline hydrochloride. Each film-coated tablet contains 10 mg amitriptyline hydrochloride.

The other ingredients are:

*Tablet core:* Colloidal silicon dioxide, corn maize starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc

*Tablet coating:* Hypromellose, macrogol 6000, macrogol (E1521), polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171), FD&C Blue #1/Brilliant Blue FCF Aluminium Lake

(E133).

**What AMDERIP 25 contains:**

The active substance is amitriptyline hydrochloride. Each film-coated tablet contains 25 mg amitriptyline hydrochloride.

The other ingredients are:

*Tablet core:* Colloidal silicon dioxide, corn maize starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc

*Tablet coating:* Hypromellose, iron oxide yellow (E172), macrogol 6000, macrogol (E1521), polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171).

**What AMDERIP 50 contains:**

The active substance is amitriptyline hydrochloride. Each film-coated tablet contains 50 mg amitriptyline hydrochloride.

The other ingredients are:

*Tablet core:* Colloidal silicon dioxide, corn maize starch, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc

*Tablet coating:* Hypromellose, iron oxide yellow (E172), iron oxide red (E172), macrogol 6000, macrogol (E1521), polyvinyl alcohol (E1203), talc (E553b), titanium dioxide (E171).

**What AMDERIP looks like and contents of the pack****AMDERIP 10:**

Round blue colored biconvex tablets debossed 1 on one side and plain on other side and are packed in polyvinyl chloride (PVC)/polyvinylidene chloride (PVdC)/aluminium blisters containing 30 film-coated tablets. The blister strips are packed in a printed carton.

**AMDERIP 25:**

Round yellow colored biconvex tablets plain on both sides and are packed in polyvinyl

chloride (PVC)/polyvinylidene chloride (PVdC)/aluminium blisters containing 30 or 60 film-coated tablets. The blister strips are packed in a printed carton.

**AMDERIP 50:**

Round brown colored biconvex tablets plain on both sides and are packed in polyvinyl chloride (PVC)/polyvinylidene chloride (PVdC)/aluminium blisters containing 30 film-coated tablets. The blister strips are packed in a printed carton.

**Holder of Certificate of Registration**

Strides Pharma SA (Pty) Ltd

106 16<sup>th</sup> Road

Building 2

Midrand

**This leaflet was last revised in**

Not applicable.

**Registration/Application number**

**AMDERIP 10:** 54/1.2/0684.681

**AMDERIP 25:** 54/1.2/0685.682

**AMDERIP 50:** 54/1.2/0686.683

**Access to the corresponding Professional Information**

To follow