Package leaflet: Information for the patient

Aniva 10 mg Film-coated Tablets
Aniva 25 mg Film-coated Tablets
Aniva 50 mg Film-coated Tablets
amitriptyline

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

1. What Aniva is and what it is used for

Amitriptyline 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 prevention in adults
- Migraine prevention 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 to all other non-drug and drug treatments, 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 Aniva

Do not take Aniva
- if you are allergic to amitriptyline 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 Aniva, 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 Aniva.

Heart rhythm disorders and hypotension may occur if you receive a high dosage of amitriptyline. This might also occur in usual doses if you have pre-existing heart disease.

Prolonged QT interval
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 Aniva. 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
- 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.

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed, 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 young adults (less than 25 years old) 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, 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.

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, 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 Aniva 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 prevention
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 taken at the same time as an anticholinergic drug (see also section 2 Other medicines and Aniva
- 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 bedwetting.

Other medicines and Aniva
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 Aniva (see section 2 Do not take Aniva)
- 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 Parkinsons disease and gastrointestinal 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.

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.

Aniva with food, drink and alcohol
It is not advised to drink alcohol during treatment with 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 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 (withholding/retaining urine), 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.

Aniva contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Aniva

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 the 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 medicine, your doctor may gradually increase the dose. If you receive doses above 100 mg daily, your doctor may need to do more frequent follow-up with you. Your doctor will instruct you whether to take the doses once daily or divide 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 Aniva
- 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 Aniva

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
The maximum period of treatment course should not exceed 3 months.
Your doctor will evaluate if the treatment should be continued after 3 months.

If you take more Aniva than you should
Contact your doctor or nearest hospital casualty department immediately. 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
- agitation
- confusion
- hallucinations
- uncontrolled movements
- low blood pressure, weak pulse, pallor
- difficulty breathing
- blue discolouration of the skin
- decreased heart rate
- drowsiness
- loss of consciousness
- coma
- various cardiac symptoms such as heart block (abnormal heart rhythm due to issue with the heart's electrical system), heart failure (failure in the functioning of the heart), hypotension (decrease in blood pressure), cardiogenic shock (a condition in which your heart suddenly

can't pump enough blood to meet your body's needs), metabolic acidosis (a condition that occurs when the body produces excessive quantities of acid), hypokalemia (decrease in the potassium level in the blood).

If you forget to take Aniva
Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Aniva
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 the medicine, 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 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

- problem with ability of the eye to change its focus from distant to near objects (and vice versa)
- congested nose.

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 1000 people
- decreased appetite
- delirium (especially in elderly patients), hallucinations (in schizophrenic patients)
- 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 (acute glaucoma)
- 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 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 (inflammation of the liver) with signs such as dark urine, weight loss and jaundice
- hot flush
- dry eyes.

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

Reporting of suspected adverse reactions
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: HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aniva

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 carton and blister after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
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 Aniva contains
The active substance is amitriptyline.
Each film-coated tablet contains amitriptyline hydrochloride equivalent to 10 mg, 25 mg or 50 mg amitriptyline.

The other ingredients in the tablet core are lactose, maize starch, copovidone, sodium starch glycolate, talc and magnesium stearate, and in the film-coating are hypromellose, titanium dioxide (E 171), macrogol, iron oxide red (E 172) and iron oxide yellow (E 172).

What Aniva looks like and contents of the pack
Aniva 10 mg are round, reddish brown film-coated tablets, marked with '10' on one side.
Aniva 25 mg are round, pale brown film-coated tablets.
Aniva 50 mg are round, reddish brown film-coated tablets, marked with '50' on one side.

Aniva 10 mg, 25 mg and 50 mg are available in blisters of 7, 10, 14, 20, 21, 28, 30, 50, 56, 60, 84, 90, 100 and 250 (50 mg only) film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland

Manufacturer
Wessling GmbH, Johann-Krane-Weg 42, Sentrup, Münster, North Rhine-Westfalen, 48149, Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Aniva 10 mg, 25 mg & 50 mg Film-coated Tablets
Malta	Amitriptyline 10 mg, 25 mg & 50 mg film-coated tablets

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