PATIENT INFORMATION LEAFLET FOR AZCURA 60, 90 & 120

SCHEDULING STATUS: S3

AZCURA 60 film-coated tablets

AZCURA 90 film-coated tablets

AZCURA 120 film-coated tablets

Etoricoxib

AZCURA 60: Contains sugar (1 mg lactose monohydrate)

AZCURA 90: Contains sugar (1,5 mg lactose monohydrate)

AZCURA 120: Contains sugar (2 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking AZCURA film-coated tablets.

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

1. What AZCURA is and what it is used for

AZCURA is a member of a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDS) and a selective cyclo-oxygenase-2 (COX-2) inhibitor.

Your doctor has prescribed AZCURA for one of the following conditions:

- relief of symptoms of rheumatoid arthritis (RA)
- treatment of ankylosing spondylitis (AS)
- short term relief of acute pain, treatment limited to a maximum period of 8 days
- treatment of acute gouty arthritis
- treatment of menstrual pain
- treatment of moderate to severe acute pain after dental surgery.

2. What you need to know before you take AZCURA

Do not take AZCURA:

- if you are allergic (hypersensitive) to etoricoxib, or any of the inactive ingredients of AZCURA (listed in section 6)
- if you have had a stomach ulcer or bleeding in the stomach or intestines in the past (characterised by blood in the stools)
- if you have an active stomach ulcer or bleeding in the stomach or intestines
- if you have a serious liver disorder
- if you have a serious kidney disorder
- if you have previously experienced any of the following after taking aspirin or other nonsteroidal anti-inflammatory medicines: asthma (wheezing or inability to breathe easily), nasal irritation, nasal polyps (overgrowths in the nose) or allergic symptoms such as swelling of the face, lips, tongue or throat and/or itching skin rash
- if you have high blood pressure which has not been adequately controlled by treatment
- if you are pregnant or breastfeeding

- if you are under 16 years of age
- if you have inflammatory bowel disease (characterised by inflammation of the bowel)
- if your doctor has diagnosed you with heart problems including heart failure (moderate or severe), chest pain (angina) or if you have had a heart attack, bypass surgery, narrow or blocked arteries of the extremities (peripheral arterial disease), or any kind of stroke (including mini-stroke or transient ischaemic attack). AZCURA may increase your risk of a heart attack and stroke and therefore it should not be taken if you have already had heart problems or a stroke.
- if you have to undergo bypass surgery of the heart.

Warnings and precautions

Take special care with AZCURA:

- if you have a history of kidney disease
- if you have a history of liver disease
- if you have a history of heart failure, heart attack or any other form of heart disease
- if you have narrow or blocked arteries of the extremities
- if you are dehydrated, for example by a prolonged period of vomiting or diarrhoea
- if you have a history of high blood pressure
- if you have a history of stroke or mini-stroke
- if you have a history of stomach bleeding or ulcers (blood in your stools)
- if you are being treated for an infection. AZCURA can mask or hide a fever, which is a sign of infection
- if you are a woman trying to become pregnant
- if you are elderly (over 65 years of age)
- if you have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.
- if you develop flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test

results (including increased white blood cells [eosinophilia] and liver enzymes) (drug reaction with eosinophilia and systemic symptoms [DRESS]).

There appears to be a higher risk of cardiovascular events with higher doses and longer duration of treatment.

Serious skin reactions may occur with AZCURA treatment.

Children and adolescents

Safety and efficacy in children have not been established. Therefore, AZCURA should not be given to children and adolescents under the age of 16 years.

Other medicines and AZCURA

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

The following medicines may cause an interaction when used in combination with AZCURA:

- Warfarin (used for the prevention of blood clots).
- Selective serotonin reuptake inhibitors (SSRIs), such as citalopram, fluoxetine or sertraline (used to treat depression).
- Rifampicin (used for the treatment of tuberculosis [TB]).
- Diuretics (water pills, used for the treatment of high blood pressure).
- ACE inhibitors and angiotensin receptor blockers (used to treat high blood pressure and heart failure).
- Lithium (used to treat depression).
- Oral contraceptive pills (used to prevent unplanned pregnancies).
- Methotrexate (used for suppressing the immune system and often used in rheumatoid arthritis).
- Ciclosporin or tacrolimus (used for suppressing the immune system).

- Hormone replacement therapy.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or diclofenac (used to treat pain and inflammation).
- Aspirin (in low doses used as a blood thinner). AZCURA can be taken with low dose aspirin to prevent heart attacks or stroke; you should not stop taking aspirin until you talk to your doctor.
- Aspirin (in high doses used to treat pain, fever and inflammation). Do not take high dose aspirin or other anti-inflammatory medicines while taking AZCURA.
- Minoxidil (used to treat high blood pressure).
- Salbutamol (used to treat asthma).
- Digoxin (used for heart failure and irregular heart rhythm).
- Ketoconazole (used for the treatment of fungal infections).
- Voriconazole and miconazole (used to treat fungal or yeast infections).

AZCURA with food, drink and alcohol

AZCURA may be taken with or without food.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking AZCURA.

DO NOT take AZCURA if you are pregnant or suspect that you are pregnant. Contact you doctor immediately.

If you take NSAIDs, including AZCURA, during pregnancy from about 20 weeks onward, it may affect your baby’s kidneys. This can reduce the amount of amniotic fluid around your baby (called oligohydramnios), and in some cases may cause kidney problems after birth. If the low fluid

continues for a long time, your baby's arms or legs may not move normally, and the lungs may not develop properly. In severe cases, your baby may need treatment after birth, such as a blood exchange or dialysis.

DO NOT take AZCURA if you are breastfeeding your baby.

Driving and using machines

AZCURA may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how AZCURA affects you.

AZCURA contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AZCURA.

3. How to take AZCURA

Do not share medicines prescribed for you with any other person.
Always take AZCURA exactly as your doctor has instructed you. Do not take more than the recommended dose for your condition.
You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of AZCURA is too weak or too strong, talk to your doctor or pharmacist.

Rheumatoid arthritis

The recommended dose is 90 mg once daily.

Ankylosing spondylitis (AS)

The recommended dose is 90 mg once daily. In some patients, 60 mg once daily may provide adequate therapeutic benefit.

Short-term relief of acute pain

The recommended dose is 90 mg or 120 mg once daily, limited to a maximum of 8 days treatment.

Acute gouty arthritis

The recommended dose is 120 mg once daily. AZCURA 120 should be used only for the acute symptomatic period, limited to a maximum of 8 days treatment.

Primary dysmenorrhoea

The recommended dose is 120 mg once daily.

Post-operative dental pain

The recommended dose is 90 mg once daily.

If you have the impression that the effect of AZCURA is too strong or too weak, talk to your doctor or pharmacist.

Doses greater than those recommended for each condition did not provide additional benefit or have not been studied. Therefore, do not exceed the dose stated above for each condition.

If you have mild liver disease, you should not take more than 60 mg a day. If you have moderate liver disease, you should not take more than 60 mg every other day. You should not use AZCURA if you have severe liver disease.

If you take more AZCURA than you should

In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take AZCURA

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your AZCURA at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

AZCURA can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.
- Drug reaction with eosinophilia and systemic symptoms (DRESS) can occur several weeks after starting AZCURA, including symptoms such as fever, swollen lymph nodes, flu-like symptoms, facial swelling, yellowing of the skin or eyes, dark urine, pale stools, cough, or shortness of breath. DRESS can affect important organs such as the liver, kidneys, lungs or heart.

These are all very serious side effects. If you have them, you may have had a serious reaction to

AZCURA. 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:

- Irregular heartbeat, irregular heart rhythm (dysrhythmia).
- Heart disorders (abnormal heart rhythm), heart failure, feeling tightness, pressure or heaviness in the chest (angina pectoris), heart attack.
- Chest pain.

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:

- Dizziness, headache.
- High blood pressure.
- Stomach pain, flatulence, heartburn, diarrhoea, nausea, constipation, black stools (melaena), vomiting of blood (haematemesis), inflamed, swollen and sore mouth (ulcerative stomatitis), inflammation (swelling) of your large intestine (colitis) and Crohn's disease (inflammatory bowel disease that causes chronic inflammation of the GI tract).
- Discolouration of the skin.
- Unusual tiredness or weakness, flu-like symptoms.
- Dry socket (inflammation and pain after a tooth extraction).

Less frequent side effects:

- Inflammation of the gastrointestinal tract, respiratory tract infection, urinary tract infection (bladder infection).
- Blood disorders (such as an abnormally low number of platelets or white blood cells), anaemia (fatigue, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat).

- Increased or decreased appetite, weight gain.
- Anxiety, depression, confusion, hallucinations (seeing or hearing things that does not exist).
- Taste alteration.
- Sleeping problems, restlessness.
- Blurred vision, eye irritation and redness.
- Ringing sound in the ears, vertigo (sensation of spinning while remaining still).
- Hot flushes, stroke, mini-stroke, inflammation of the blood vessels.
- Coughing, shortness of breath, nose bleeds, difficulty in breathing.
- Stomach pain, dry mouth, vomiting, blood in the stools, changes in your bowel habits, stomach ulcer.
- Liver problems.
- High levels of potassium in your blood, changes in blood or urine tests relating to your kidneys, kidney problems.

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AZCURA.

5. How to store AZCURA

- Store at or below 25 °C.
- Keep the blister strip in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label or carton.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AZCURA contains

The active ingredient is etoricoxib.

The other ingredients are sodium laurilsulfate, microcrystalline cellulose, low-substituted hydroxypropyl cellulose, anhydrous calcium hydrogen phosphate, croscarmellose sodium, anhydrous colloidal silica, magnesium stearate, Instacoat Universal Green (for AZCURA 60 and AZCURA 120), Instacoat Universal White (for AZCURA 90), lactose monohydrate and glycerol triacetate.

What AZCURA looks like and contents of the pack

AZCURA 60: Light green to bluish-green, round, biconvex, film-coated tablet debossed ‘60’ on one side and plain on the other side. The tablet should be free of all physical defects.

AZCURA 90: White to off-white, round, biconvex, film-coated tablet debossed ‘90’ on one side and plain on the other side. The tablet should be free of all physical defects.

AZCURA 120: Green, round, biconvex, film-coated tablet debossed ‘120’ on one side and plain on the other side. The tablet should be free of all physical defects.

Silver aluminium/aluminium blister strips containing 7 tablets per blister strip.

AZCURA 60: 28 tablets will be packed into a cardboard box.

AZCURA 90 and 120: 7 or 28 tablets will be packed into a cardboard box.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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22 Karee Street

Centurion, Pretoria

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Tel: 012 748 6400

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AZCURA 60: 47/3.1/0546

AZCURA 90: 47/3.1/0547

AZCURA 120: 47/3.1/0548

Date of registration

30 June 2020.

Access to the corresponding Professional Information

The Professional Information is accessible at https://www.zydus.co.za/ or may be requested by contacting 012 748 6400.