

Ansures Extended Release Tablet 500mg

Metformin Hydrochloride (500mg)

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What *Ansures* is used for

Ansures is used to treat type 2 (non-insulin dependent) diabetes mellitus in adults, when dietary management and exercise alone does not result in adequate control of blood sugar. *Ansures* may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.

How *Ansures* works

Ansures contains the active ingredient metformin hydrochloride and belongs to a group of medicines called biguanides. This medicine works by lowering the amount of sugar in the blood. Your doctor may prescribe metformin for you to take on its own or in combination with other oral antidiabetic medicines or insulin.

Before you use *Ansures*

- When you must not use it

Do not take *Ansures* if:

- You are allergic to medicines containing metformin or any other biguanide also any of the ingredients listed at the end of this leaflet.
- you have ketosis (this is a symptom of uncontrolled diabetes in which substances called 'ketone bodies' accumulate in the blood – you may notice that your breath has an unusual, fruity odour).
- you have long-term kidney or liver problems.
- you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration.

- you have a severe infection or have recently suffered a severe injury.
- you have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
- you are a heavy drinker of alcohol.
- If you severely reduced kidney function.
- If you have lactic acidosis [too much lactic acid in the blood (see 'Risk of lactic acidosis' below)] or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms of acidosis may include stomach pain, abnormal breathing and drowsiness (if severe).

Pregnancy and lactation

Do not take *Ansures* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Ansures* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

You should tell your doctor if you are pregnant or breast-feeding, before you start using *Ansures*.

Ansures may cause a very rare, but very serious side effect called lactic acidosis (kidneys not working properly).

Stop taking *Ansures* for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as

- severe vomiting,
- diarrhea
- fever
- exposure to heat or if you drink less fluid than normal.

Stop taking *Ansures* and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- Vomiting

- Stomach ache (abdominal pain)
- Muscle cramps
- A general feeling of not being well with severe tiredness
- Difficulty in breathing

Lactic acidosis is a medical emergency and must be treated in a hospital.

During treatment with *Ansures*, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:

- Cimetidine
- Amiloride
- Digoxin
- Morphine
- Procainamide
- Quinidine
- Quinine
- Triamterene
- Trimethoprim
- Vancomycin.

- The individual should be closely observe for loss of blood glucose control when thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs.

How to use *Ansures*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Swallow the tablets whole with a glass of water, do not chew.

Usually you will start treatment with 500 milligrams Ansures. After you have been taking Ansures for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Ansures. Normally, you should take the tablets once a day, with your evening meal.

In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

Children: Ansures should not be used in children.

Elderly: Due to the potential for decreased kidney function in elderly subjects, the metformin dosage should be adjusted based on kidney function. Regular assessment of kidney function is necessary.

- When to use it

Use as directed by your doctor or pharmacist.

Taking Ansures during or with your evening meal will reduce the chance of a stomach upset.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

- How long to use it

Continue taking Ansures for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause lactic acidosis is more likely and this is a medical emergency requiring treatment in hospital.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Ansures.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Ansures to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low. Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, Ansures by itself is unlikely to affect how you drive or operate machinery.

Side effects

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

If you notice any of the following, stop taking Ansures and see your doctor immediately:

- unexpected weight loss
- very severe nausea or vomiting
- very fast breathing which you cannot stop
- stomach pains or feeling cold

These can be signs of serious problems with your diabetes and may mean you have a very rare side effect called “lactic acidosis” (too much acid in the blood). If this happens, see a doctor as you will need treatment straight away.

- Abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice. If you develop yellowing of the eyes and/or skin contact your doctor immediately.

Other possible side effects are listed by frequency as follows:

Very common (affects more than 1 person in 10):

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.

Common (affects less than 1 person in 10, but more than 1 person in 100):

- Taste disturbance

Very rare (affects less than 1 person in 10,000):

- Decreased vitamin B12 levels
- Skin rashes including redness, itching and hives.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Ansures

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White tablets, oblong with length 17.6 mm $\pm$ 0.25mm, width 8.0mm $\pm$ 0.25mm, thickness 6.65mm $\pm$ 0.15mm.

- Ingredients

- Active ingredient(s)
500mg of Metformin hydrochloride in extended release form.

- Inactive ingredients
Hydroxypropyl Methylcellulose,
Silicon Dioxide, Magnesium Stearate.

- MAL number(s):
MAL10080062AZ

Manufacturer

SIU GUAN CHEM. IND.CO.,LTD
No. 128 Shin Min Road, Chia Yi,
Taiwan.

Product Registration Holder

Averroes Pharmaceuticals Sdn. Bhd.
03-08-01 & 03-09-01, Block 3, Presint
Alami,
Worldwide Business Centre II,
Persiaran Akuatik, Section 13,
40100 Shah Alam, Selangor.
Malaysia

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