ACNETANE causes severe birth defects. It should not be taken by pregnant women, women intending to become pregnant or sexually active women in their fertile years not using at least two methods of contraception as severe malformations may occur during pregnancy.

SCHEDULING STATUS:

S5

ACNETANE 10 mg

ACNETANE 20 mg

soft gelatin capsules

Isotretinoin

Sugar free

Read all of this leaflet carefully before you start taking ACNETANE

- 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.
- ACNETANE 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 ACNETANE is and what it is used for

ACNETANE contains per capsule 10 mg or 20 mg isotretinoin.

ACNETANE is a chemical derivative of vitamin A and it is used to treat severe, resistant, nodular acne, after other anti-acne medicines have failed to help. It works by decreasing the activity of the sebaceous glands in the skin and therefore prevents the formation of acne lesions.

ACNETANE is given as a 16-24 week first course of treatment, depending on the daily dose taken. A second course of treatment may be prescribed, if needed, 8 weeks after completing the first course.

ACNETANE is a scheduled medicine and not a cosmetic. It should therefore be kept in a safe place and not be shared with any person who does not have a valid prescription to use it.

2. What you need to know before you take ACNETANE

Do not take ACNETANE:

- if you are hypersensitive (allergic) to isotretinoin or any of the other ingredients of ACNETANE, to any other medicines, or to soya (listed in section 6).
- If you are pregnant or intend to become pregnant or breastfeeding your baby (see important warning for females below).
- If you have liver disease.
- If you have very high levels of blood fats (e.g. high cholesterol or triglycerides).
- If you have very high levels of vitamin A in your body (hypervitaminosis A).
- If you are receiving treatment with tetracyclines (a type of antibiotic) at the same time (see “Other medicines and ACNETANE”).

Warnings and precautions

- Please consult your doctor, pharmacist or other healthcare professional for advice, if you are taking other medicines on a regular basis, including complementary or traditional medicines, prescription medicines and medicines bought without a prescription, especially tetracycline antibiotics, vitamin A and other anti-acne medicines. The use of ACNETANE with these medicines may cause undesirable interactions.
- Exfoliating anti-acne preparations should NOT be used while you are taking ACNETANE. Mild topical products may be used if recommended by your doctor.

  NOTE: It is important that you do not take vitamin A supplements while on ACNETANE. Make sure that any multivitamins you take do not contain vitamin A.
- Do not have any wax treatment to remove hair while you take ACNETANE Capsules and for 6 months after you stop treatment.
- ACNETANE makes your skin sensitive to the sun and UV radiation. Do NOT use a sunlamp. Avoid the sun as much as possible. Wear a good sunscreen, protective clothing and a hat when outdoors.
- ACNETANE has been associated with serious skin reactions. Any rash may become serious. Stop using ACNETANE and call your doctor right away if you develop conjunctivitis (red or inflamed eyes like “pink eye”), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- ACNETANE may cause dry eyes. If you wear contact lenses, you may need to use an eye lubricating solution or wear your spectacles while you take ACNETANE.
- ACNETANE may change your night vision. If this happens, do not drive or do anything else that requires you to see well. Also, speak to your doctor. This will revert to normal after the treatment.
- Do not donate blood while you are taking ACNETANE or for 30 days after you stop taking it. This is to avoid the possibility of a pregnant woman receiving your blood that contains ACNETANE.
- Acnetane can affect your liver. Liver function tests should be conducted prior to onset of therapy and one month after commencement of treatment. Thereafter liver function tests should be conducted at three monthly intervals.

- There have been reported cases of a disorder related to high pressure in the brain. Call your doctor if you experience visual disturbances, headache, nausea and vomiting.
- Acnetane may lead to psychosis, depression and infrequently suicidal behaviour.
- Acnetane may result in an increase in cholesterol levels.
- Acnetane therapy can cause abdominal pain, severe diarrhoea or rectal bleeding. Contact your doctor immediately if you experience these symptoms.
- Acnetane can cause skeletal disorders associated with bone overgrowth, hardening of muscles and tendons that cause stiffness.
- Patients with renal insufficiency should be started on a low dose and your doctor can increase the dose up to the maximum tolerated dose.
- ACNETANE has been prescribed particularly for you. Never share medicines prescribed for you with others.

Other medicines and ACNETANE

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

Concomitant treatment with tetracyclines is contraindicated as cases of benign intracranial hypertension have been reported. Concomitant use of Vitamin A, including dietary supplements is not recommended due to their additive toxic effects which may result in hypervitaminosis A.

ACNETANE with food and drink

Take ACNETANE with food or milk once or twice a day.

Pregnancy, breastfeeding and fertility

IMPORTANT INSTRUCTIONS AND WARNINGS FOR FEMALE PATIENTS:

You must not take ACNETANE if you are or suspect that you may be pregnant, if you intend becoming pregnant, or if you are breastfeeding.

- **ACNETANE causes severe birth defects. If you have child-bearing potential you must use two reliable methods of contraception while on ACNETANE, starting one month before ACNETANE therapy is started and continuing for one month after stopping ACNETANE.**
- **ACNETANE therapy must start on the Second or third day of menstruation. A pregnancy test is done 2 weeks before starting treatment and may be done during ACNETANE treatment.**
- **If you have child-bearing potential you must sign the Consent Form before starting ACNETANE therapy.**

NOTE: If you do become pregnant while you are taking ACNETANE, there is a high risk of severe birth defects to your baby.

Please note that your doctor must give you the following information with your prescription:

- **Patient Information Leaflet**
- **Brochure on Birth Control**
- **Female Patient Information and Consent Form**

Driving and using machines

Less frequent side effects such as drowsiness and visual disturbances have been reported (see section 4). If this happens to you, you should not drive or operate machinery.

Cases of decreased night vision have occurred during ACNETANE therapy and some have persisted after therapy. Because it can happen suddenly, you must be aware of the potential problem and be cautious when you drive or operate machinery.

It is not always possible to predict to what extent ACNETANE may interfere with your daily activities. You

should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ACNETANE affects you.

ACNETANE contains ethylparaben and soybean oil

- Ethylparaben may cause allergic reactions.
- If you are allergic to peanut or soya, do not take ACNETANE.

3. How to take ACNETANE

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

  Always use ACNETANE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Take ACNETANE with food or milk once or twice a day.
- The dose of ACNETANE will be different for different patients. It is based on your bodyweight. Your doctor may later change your dosage depending on your response and if side effects occur.

  NOTE: Acne may be worsened at first. Do not stop taking the medicine as it is essential that you continue treatment during this phase.
- The usual dose of ACNETANE for adult and teenagers is 0,5 to 1,0 mg per kg.
- A treatment course is usually 4 - 8 months depending on the daily dose. After stopping treatment, many patients notice a further improvement and repeated courses are not usually needed. If a definite relapse does occur, a repeat course may then be given but should only be started at least 8 weeks after stopping the first course.

Your doctor will tell you how long your treatment with **ACNETANE** will last. Do not stop treatment early unless you have spoken to your doctor.

If you have the impression that the effect of **ACNETANE** is too strong or too weak, tell your doctor or pharmacist.

If you take more ACNETANE than you should

Acute toxicity of ACNETANE is low. However, in case of overdose or accidental intake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ACNETANE

If you miss a dose, take it as soon as you can. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects

ACNETANE can have side effects.

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

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

- Serious (anaphylactic) reactions: difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips and mouth. Also sudden swelling of the hands, feet and ankles.

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

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

- Serious skin rashes (erythema multiforme, Stevens- Johnson syndrome, and toxic epidermal necrolysis), which are potentially life-threatening and require immediate medical attention. These appear initially as circular patches often with central blisters usually on arms and hands or legs and feet, more severe rashes

may include blistering of the chest and back.

Additional symptoms such as infection of the eye (conjunctivitis) or ulcers of the mouth, throat or nose may occur. Severe forms of rash may progress to widespread peeling of the skin which can be life threatening. These serious skin rashes are often preceded by headache, fever, body aches (flu-like symptoms).

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

- Anaemia (weakness, tiredness, pale skin)
- More liable to get infections (occurs if white blood cells are affected)
- Bruising, bleeding or clotting more easily (occur if clotting cells are affected)
- Headache
- Red, swollen and itchy eyelids
- Dry eyes, Conjunctivitis (Pink Eye)
- Nose bleeds and dry nose
- Raised liver enzymes (seen in blood tests)
- Chapped lips
- Dryness, itching or crusting of the skin
- Peeling of skin on palms of hands or soles of feet
- Red or pink skin rash
- Skin fragility
- Joint pain, back pain or muscle pain
- Changed levels of fats in the blood (including HDL or triglycerides)
- Decreased high-density lipoprotein
- Increased blood sugar

- Blood in urine
- Protein in urine

Less frequent side effects

- Swollen lymph nodes
- Excessive thirst; frequent need to urinate; blood tests show an increase in your blood sugar. These can all be signs of diabetes.
- High calcium in urine
- Depression
- Aggressive tendencies
- Anxiety
- Mood changes
- Suicidal thoughts or suicide attempt
- Headache with visual disturbances
- Seizures
- Drowsiness (Sleepiness)
- Blurry or cloudy vision
- Decreased night vision
- Colour blindness
- Cloudy surface on the eye
- Sensitivity of eyes to light
- Poor hearing
- Inflammation of blood vessels
- Wheezing or coughing
- Hoarseness (voice change)
- Severe stomach pain, bloody diarrhoea, nausea or vomiting
- Yellowing of the eyes or skin

- Hair loss
- Excessive facial, chest and back hair in women
- Severe or worsened acne
- Inflammation and abnormal changes to the nails
- Redness of the face or cheeks
- Sensitivity of the skin to heat
- Darkening of areas on the skin
- Increased sweating
- Increase of small, red ,“Cobberstone-like” bumps on skin
- General feeling of unwellness or discomfort
- Bacterial infection

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 nurse. This includes any possible side effects not listed in this leaflet. 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 ACNETANE.

Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via Adcock.AEReports@adcock.com.

5. How to store ACNETANE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Store at or below 25 °C, protected from light and moisture.

Do not remove from the outer container until required for use.

Return expired, unknown or unused medicine to your pharmacist for disposal.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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

6. Contents of the pack and other information

The active ingredient in each ACNETANE 10 mg capsule contains 10 mg isotretinoin.

The active ingredient in each ACNETANE 20 mg capsule contains 20 mg isotretinoin.

The other ingredients are

Capsule filling:

Butylated Hydroxyanisole

Edetate Disodium

White wax

Soybean Oil

Capsule Shell:

Amaranth (CI 16185)

Brilliant Blue (CI 42090)

Ethylparaben

Gelatin

Glycerin

Polyethylene glycol 400

Titanium Dioxide

What ACNETANE looks like and contents of the pack

10 mg Capsules: Pink oval shaped soft gelatin capsule containing a yellow oily suspension, available in blister packs containing 60 capsules.

20 mg Capsules: Purple oval shaped soft gelatin capsule containing a yellow oily suspension, available in blister packs containing 60 capsules.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand ,1685

Customer Care: 0860 ADCOCK / 232625

Name of manufacturer:

Shanghai Sine Wanxiang Pharmaceuticals Co., Ltd

No 217 Zchaochong Road

Qingpu District,

Shanghai

P.R China

This leaflet was last revised in

10 October 2024

Registration number (s)

10 mg Capsules: 34/13.4.2/0356

20 mg Capsules: 34/13.4.2/0357

Botswana:		
S2	Acnetane 10 mg (60's)	BOT1302313
S2	Acnetane 20 mg (60's)	BOT1302314

Mauritius:		
	10 mg Capsules:	R8977/02/14
	20 mg Capsules:	R9080/02/14

Namibia:		
NS3	Acnetane 10 mg	05/13.4.3/0337
NS3	Acnetane 20 mg	05/13.4.3/0338