Approved Patient Information Leaflet for Medicines for Human Use: SUPATANE 8 mg & 16 mg

WARNING

SUPATANE CAUSES SEVERE BIRTH DEFECTS

Women must use effective contraception

Do not use if you are pregnant or think you may be pregnant

SCHEDULING STATUS: S5

SUPATANE 8 mg capsule

SUPATANE 16 mg capsule

Isotretinoin

Sugar free

It is a criminal act to give SUPATANE to any person who does not have a valid prescription.

Please read this leaflet carefully before you use SUPATANE capsules. This leaflet does not tell you all the information known about SUPATANE capsules. If you have any questions or are worried about any of this information, please speak to your doctor or pharmacist.

Read all of this leaflet carefully before you start taking SUPATANE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your Health care provider.
- SUPATANE 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.

- If you get any side effects, talk to your Health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What SUPATANE is and what it is used for

SUPATANE contains isotretinoin – a substance related to vitamin A, and a group of medicines called retinoids (for treatment of acne).

SUPATANE is used to treat severe types of acne (such as nodular or conglobate acne, or acne that is at risk of causing permanent scarring) in adults and adolescents from 12 years of age only after puberty.

You will use SUPATANE when your acne has not got better with anti-acne treatments, including antibiotics and skin treatments.

SUPATANE treatment must be supervised by a dermatologist (a doctor specialised in the treatment of skin problems).

2. What you need to know before you take SUPATANE

Do not take SUPATANE

- If you are pregnant or breastfeeding

- If there is any chance you could become pregnant, you must follow the precautions under "Pregnancy prevention programme", see section on "Warnings and precautions"
- If you are hypersensitive (allergic) to isotretinoin, peanut or soya or any other ingredients of this medicine (listed in section 6)
- 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 SUPATANE")

If any of these apply to you, go back to your doctor before taking any SUPATANE.

Warnings and precautions

Take special care before taking SUPATANE:

If you have ever had any kind of mental health problems. This includes depression, aggressive tendencies or mood changes. It also includes thoughts about hurting yourself or ending your life. This is because your mood may be affected while taking SUPATANE.

Pregnancy prevention programme

Do not use SUPATANE if you are pregnant, intend becoming pregnant or are breastfeeding.

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

- **If you have child-bearing potential, you must sign the Consent Form before starting SUPATANE therapy.**

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

Patient Information Brochure

Brochure on Birth Control

Female Patient Information and Consent Form

Women who are pregnant must not take SUPATANE

This medicine can seriously harm an unborn baby (the medicine is said to be 'teratogenic') – it can cause serious abnormalities of the unborn baby's brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland). It also makes a miscarriage more likely. This may happen even if SUPATANE is taken only for a short time during pregnancy.

- You must not take SUPATANE if you are pregnant or if you think you might be pregnant
- You must not take SUPATANE if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby
- You must not take SUPATANE if you could get pregnant during treatment
- You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed SUPATANE under strict rules. This is because of the risk of serious harm to the unborn baby

These are the rules:

- Your doctor must explain the risk of harm to the unborn baby - you must understand why you must not get pregnant and what you need to do to prevent getting pregnant
- You must have talked about contraception (birth control) with your Health care provider. The doctor will give you information on how not to get pregnant. The doctor may send you

to a specialist for contraception advice

- Before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with SUPATANE.

Women must use effective contraception before, during and after taking SUPATANE

- You must agree to use at least one very reliable method of contraception (for example an intrauterine device or contraceptive implant) or, two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor or health care provider which methods would be suitable for you
- You must use contraception for a month before taking SUPATANE, during treatment and for a month afterwards
- You must use contraception even if you do not have periods or you are not sexually active (unless your doctor or health care provider decides this is not necessary).

Women must agree to pregnancy testing before, during and after taking SUPATANE

- You must agree to regular follow-up visits, ideally every month
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, 1 month after stopping SUPATANE (unless your doctor or health care provider decides this is not necessary in your case)
- You must agree to extra pregnancy tests if your doctor or health care provider asks you
- You must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body
- Your doctor or health care provider will discuss all these points with you, using a checklist and will ask you (or a parent/guardian) to sign it. This form confirms that you have been told about the risks and that you will follow the rules above.

If you get pregnant while taking SUPATANE, **stop taking the medicine straight away,** and contact your Health care provider. Your doctor or health care provider may send you to a specialist for advice.

Also, if you become pregnant within one month after you stop taking SUPATANE, you should contact your Health care provider. Your doctor or health care provider may send you to a specialist for advice.

Your doctor or health care provider has written information on pregnancy prevention for the users of SUPATANE which should be given to you.

A new prescription is needed for more treatment. Each prescription is only valid for 7 days.

Advice for men

The levels of oral retinoid in the semen of men taking SUPATANE are too low to harm their partners' unborn baby. However, you must never share your medication with anyone.

Additional precautions

You should never give this medicine to another person. Please take any unused capsules to your pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 1 month after stopping SUPATANE because an unborn baby could be harmed if a pregnant patient receives your blood.

Mental health problems

You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor or health care provider about.

Advice for all patients

- Tell your doctor if you have ever had any mental illness (including depression, suicidal behaviour or psychosis), or if you take medicines for any of these conditions
- Severe Skin reactions (e.g. Erythema Multiforme (EM), Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)) have been reported with the use of isotretinoin. The rash may progress to widespread blistering or peeling of the skin. You should also look for ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes)
- SUPATANE may cause severe allergic reactions some of which can affect skin in the form of eczema, hives and bruises or red patches on arms and legs. If you develop an allergic reaction, stop taking SUPATANE, seek urgent advice from a doctor or health care provider and tell him that you are taking this medicine
- Cut down on intensive exercise and physical activity. SUPATANE can cause muscle and joint pain particularly in children and teenagers undertaking vigorous physical activity
- SUPATANE has been associated with inflammatory bowel disease. Your doctor or health care provider will take you off SUPATANE if you have severe bloody diarrhoea without any history of gastrointestinal disorders
- SUPATANE may cause dry eyes, intolerance to contact lenses and visual difficulties including decreased night vision. Tell your doctor or health care provider if you have any of these symptoms. Your doctor or health care provider may ask you to use lubricating eye ointment or tear replacement therapy. If you use contact lenses and you have developed intolerance to contact lenses, you may be advised to wear glasses during the treatment. Your doctor or health care provider may refer you to a specialist for advice if you develop visual difficulties and you may be asked to stop taking SUPATANE
- Benign intracranial hypertension has been reported with SUPATANE use and in some cases where SUPATANE was used together with tetracyclines (a type of antibiotic). Stop taking SUPATANE and seek urgent advice from your doctor or health care provider if you develop symptoms like headache, nausea, vomiting and visual disturbances. Your doctor

or health care provider may refer you to a specialist to check for swelling of optic disk in the eye (papilloedema)

- SUPATANE may increase liver enzyme levels. Your doctor or health care provider will do blood tests before, during and after SUPATANE treatment to check these levels. If they stay high, your doctor or health care provider may lower your dose or take you off SUPATANE
- SUPATANE commonly increases blood fats, such as cholesterol or triglycerides. Your doctor or health care provider will test these levels before, during and after SUPATANE treatment. It is best that you do not drink alcoholic drinks or that you at least reduce the amount you usually drink while on treatment. Tell your doctor or health care provider if you already have high blood fats, diabetes (high blood sugars), are overweight, or an alcoholic. You may need blood tests more often. If your blood fats stay high, your doctor or health care provider may lower your dose, or take you off SUPATANE
- Tell your doctor or health care provider if you have any kidney problems. Your doctor or health care provider may start you on a lower dose of SUPATANE and then increase it to the maximum tolerated dose
- Your doctor or health care provider may monitor blood sugar levels during treatment, particularly if you already have diabetes, are overweight, or are an alcoholic
- Your skin is likely to get dry. Use a skin moisturising ointment or cream and a lip balm during treatment. To prevent skin irritation, you should avoid using exfoliating or anti-acne products
- Avoid too much sun and do not use a sunlamp or sunbed. Your skin may become more sensitive to sunlight. Before you go out in the sun, use a sun-protection product with a high protection factor (SPF 15 or higher)
- Do not have any cosmetic skin treatments. SUPATANE may make your skin more fragile. Do not have any waxing (hair removal), dermabrasion or laser treatments (removing horny skin or scars) during treatment, or for at least 6 months after treatment. They could cause scarring, skin irritation, or rarely, changes in the colour of your skin

Children and adolescents

The use of SUPATANE in children under the age of 12 is not recommended. This is because it is not known if it is safe or effective in this age group.

Use in adolescents over 12 years of age only after puberty.

Other medicines and SUPATANE

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

- Do not take vitamin A supplements or tetracyclines (a type of antibiotic) or use any skin treatments for acne while you are on SUPATANE.
- It is good to use moisturisers and emollients (skin creams or preparations that prevent water loss and have a softening effect on the skin).
- Avoid the use of topical keratolytic or exfoliative anti-acne products while you are on SUPATANE as using them together may make skin irritation worse.

SUPATANE with food and drink

It's best to avoid alcohol while taking isotretinoin capsules, or at least keep the amount you drink to a minimum. This is because there's a risk of damage to your liver.

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 or health care provider for advice before taking this medicine.
For more information on contraception, pregnancy and breastfeeding, see section 2 “Pregnancy prevention programme”.

Driving and using machines

You may not see as well at night during your treatment. This can happen suddenly. In rare cases this has continued after the treatment has stopped. Drowsiness and dizziness have been

reported very rarely. If this happens to you, you should not drive or operate machinery.

Important information about some of the ingredients of SUPATANE

SUPATANE contains soya-bean oil. If you are allergic to peanut or soya, do not use SUPATANE.

3. How to take SUPATANE

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

Always take SUPATANE exactly as your doctor or health care provider has told you. Check with your doctor or health care provider if you are not sure.

The usual dose unless otherwise recommended by your doctor or health care provider is 0,4 mg per kilogram body weight per day (0,4 mg/kg/day). So, if you weigh 60 kg, your dose will usually start at 24 mg a day.

If you have severe kidney problems, you will usually start on a lower dose (such as 8 mg/day) which will be increased up to the highest dose your body can tolerate. If your body cannot tolerate the recommended dose, you may be prescribed a lower dose: that can mean you are treated for longer and
your acne might be more likely to come back.

Duration of administration

Your doctor or health care provider will tell you how long your treatment with SUPATANE will last.

A course of treatment usually lasts for 16 to 24 weeks. Most patients only need one course. Your acne may continue to improve for up to 8 weeks after treatment. You won't usually start another course until then.

Some people find their acne gets worse during the first weeks of treatment. It usually improves as treatment goes on.

After a few weeks your doctor or health care provider may adjust your dose. This depends on how you are getting on with your medicine. For most patients the dose will be between 0,4 and 0,8 mg/kg/day. If you think that SUPATANE is too strong or too weak, talk to your Health care provider.

Method of administration

Take the capsules once or twice daily.

Take on a full stomach (preferably after your main meal). Swallow them whole, with a drink or a mouthful of food.

If you take more SUPATANE than you should

In the event of overdosage, consult your Health care provider. If neither is available, contact the nearest hospital or poison centre.

If you forget to take SUPATANE

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 a double dose (two doses close together).

4. Possible side effects

SUPATANE can have side effects.

Not all side effects reported for SUPATANE are included in this leaflet. Some of the side effects associated with the use of isotretinoin are related to the dose.

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

- swelling of the hands, feet and ankles, face, lips and mouth or throat which may cause difficulty in swallowing or breathing,
- sudden tight chest, shortness of breath and wheezing, particularly if you have asthma,
- rash or itching,
- fainting,
- serious skin rashes also called 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),
- some people have had thoughts about hurting themselves or ending their own lives (suicidal thoughts), have tried to end their own lives (attempted suicide), or have ended their lives (suicide).

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

- existing depression getting worse,
- becoming violent or aggressive,
- trouble moving arms or legs, painful, swollen, bruised areas of the body, dark-coloured urine, reduced or no urine output, confusion or dehydration. These are signs of rhabdomyolysis,

- difficulty urinating (passing water), swollen and puffy eyelids, feeling excessively tired. These may be signs of kidney inflammation,
- lasting headache, along with feeling sick (nausea), being sick (vomiting) and change in your eyesight including blurred vision. These may be signs of benign intracranial hypertension, especially if SUPATANE is taken with antibiotics called tetracycline,
- severe abdominal (tummy) pain, with or without severe bloody diarrhoea, feeling sick (nausea) and being sick (vomiting). These can be signs of serious gut conditions,
- blurred vision.

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:

- Dryness of the skin, especially of the lips and face; inflamed skin, chapped and inflamed lips, rash, mild itching and slight peeling. Use a moisturising cream from the start of treatment
- Skin becomes more fragile and redder than usual, especially the face
- Back pain; muscle pain; joint pain particularly in children and teenagers. To avoid making any bone or muscle problems worse, cut down on intensive physical activity while you're on SUPATANE.
- Inflammation of the eye (conjunctivitis) and eyelid area; eyes feel dry and irritated. Ask a pharmacist for suitable eye drops. If you get dry eyes and wear contact lenses, you may need to wear glasses instead.
- Raised liver enzymes seen in blood tests.
- Changed levels of fats in the blood (including HDL or triglycerides).
- Bruising, bleeding or clotting more easily - if clotting cells are affected.
- Anaemia – weakness, dizziness, pale skin – if red blood cells are affected.
- Headache.
- Higher levels of cholesterol in the blood.

- Protein or blood in the urine.
- More liable to get infections - if the white blood cells are affected.
- Inside of the nose becomes dry and crusted, causing mild nosebleeds.
- Sore or inflamed throat and nose.
- Allergic reactions such as rash, itchiness. If you have any allergic reaction, stop taking SUPATANE and contact your doctor

Less frequent side effects:

- Hair loss (alopecia). This is usually only temporary. Your hair should return to normal after the treatment ends.
- You may see less well at night; colour blindness and colour vision gets worse.
- Sensitivity to light may increase; you may find that you need to wear sunglasses to protect your eyes from too bright sunlight.
- Other sight problems including blurred vision, distorted vision, cloudy surface on the eye (corneal opacity, cataracts).
- Excessive thirst; frequent need to urinate; blood tests show an increase in your blood sugar. These can all be signs of diabetes.
- Acne can get worse in the first few weeks, but symptoms should improve with time.
- Skin inflamed, swollen, and darker than usual, especially on the face.
- Excess sweating or itching.
- Arthritis; bone disorders (delayed growth, extra growth and changes to bone density); growing bones may stop growing.
- Calcium deposits in soft tissue, sore tendons, high levels of muscle breakdown products in your blood if you exercise vigorously.
- Increased sensitivity to light.
- Bacterial infections at the base of the nail, changes to nails.
- Thickened scarring after surgery.

- Increased body hair.
- Convulsions, drowsiness, dizziness.
- Lymph glands may become swollen.
- Dry throat, hoarseness.
- Hearing difficulties.
- Generally feeling unwell.
- High levels of uric acid in the blood.

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 SUPATANE**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store SUPATANE

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package in order to protect from light and moisture.

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 SUPATANE contains

The active substance is isotretinoin.

The other ingredients are:

Capsule content: sorbitane oleate, soya-bean oil refined, stearoyl macrogolglycerides

SUPATANE 8 mg capsule

Capsule (size 3) cap and body: gelatine, red iron oxide (E172), titanium dioxide(E171)

SUPATANE 16 mg capsule

Capsule (size 1) cap and body: gelatine, indigocarmine (E132), titanium dioxide(E171), yellow iron oxide (E172)

What SUPATANE looks like and contents of the pack

SUPATANE 8 mg capsule (size 3 cap) with an orange body and cap, containing an orange waxy paste.

SUPATANE 16 mg capsule (size 1 cap) with a white body and light green cap, containing an orange waxy paste.

SUPATANE 8 mg & 16 mg capsules are packaged in thermosealed blisters that consist of white PVC foil and aluminium foil.

Packed in blisters containing 7, 14, 10 capsules.

Blisters are packed in boxes containing 28, 30, 56, 60 capsules.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

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REGISTRATION NUMBERS

SUPATANE 8 mg capsule: 51/13.4.2/0006

SUPATANE 16 mg capsule: 51/13.4.2/0007

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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