PATIENT INFORMATION LEAFLET

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
2. What you need to know before you take ACNETANE
3. How to take ACNETANE
4. Possible side effects
5. How to store ACNETANE
6. Contents of the pack and other information

PATIENT INFORMATION 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 health care 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 peanuts 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 16-24 weeks 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 health care 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 is 10 mg isotretinoin.
The active ingredient in each ACNETANE 20 mg capsule is 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 Zhaochong 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

PASIËNT INLIGTINGSBILJET

ACNETANE veroorsaak ernstige geboortedefekte. Dit moet nie geneem word deur swanger vroue, vroue wat van plan is om swanger te raak of seksueel-aktiewe vroue in hul vrugbare jare, wat nie ten minste twee metodes van voorbehoeding gebruik nie, aangesien ernstige misvormings tydens swangerskap kan voorkom.

SKEDULERINGSTATUS:

S5

ACNETANE 10 mg
ACNETANE 20 mg
sagte gelatien kapsules

Isotretinoïen
Suikervry

Lees hierdie hele biljet noukeurig deur voordat u ACNETANE begin neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ACNETANE is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat ACNETANE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ACNETANE neem
3. Hoe om ACNETANE te neem
4. Moontlike newe-effekte
5. Hoe om ACNETANE te bêre
6. Inhoud van die verpakking en ander inligting

PASIËNT INLIGTINGSBILJET

1. Wat ACNETANE is en waarvoor dit gebruik word

ACNETANE bevat 10 mg of 20 mg isotretinoïen per kapsule.
ACNETANE is 'n chemiese verbuiging van vitamien A en dit word gebruik om ernstige, weerstandige, nodulêre aknee te behandel, nadat ander anti-aknee medisyne nie gehelp het nie. Dit werk deur die aktiwiteit van die talgkliere in die vel te verminder en voorkom dus die vorming van aknee letsels.
ACNETANE word gegee as 'n eerste kursus wat 16-24 weke duur, afhangende van die daaglikse dosis wat geneem word. 'n Tweede kursus van behandeling kan, indien nodig, 8 weke na voltooiing van die eerste kursus voorgeskryf word.
ACNETANE is 'n geskeduleerde medisyne en nie 'n kosmetiese middel nie. Dit moet dus op 'n veilige plek gehou word en nie gedeel word met enige persoon wat nie 'n geldige voorskrif het om dit te gebruik nie.

2. Wat u moet weet voordat u ACNETANE neem

Moenie ACNETANE neem nie:

- Indien u hipersensitief (allergies) is vir isotretinoïen of enige van die ander bestanddele van ACNETANE, vir enige ander medisyne of vir soja (gelys in afdeling 6).
- Indien u swanger is of van plan is om swanger te raak, of u baba te borsvoed (sien belangrike waarskuwing vir vroue hieronder).
- Indien u lewersiekte het.
- Indien u baie hoë vlakke van bloedvette het (bv. hoë cholesterol of trigliseriede).
- Indien u baie hoë vlakke van vitamien A in u liggaam het (hipervitaminose A).
- Indien u terselfdertyd behandeling met tetrasikliene ('n tipe antibiotika) ontvang (sien "Ander medisyne en ACNETANE").

Waarskuwings en voorsorgmaatreëls

- Raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies, indien u ander medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne, voorskrifmedisyne en medisyne wat sonder voorskrif gekoop word, veral tetrasiklien antibiotika, vitamien A en ander anti-aknee medisyne. Die gebruik van ACNETANE met hierdie medisyne kan ongewenste interaksies veroorsaak.
- Afskilferende anti-aknee middels moet NIE gebruik word terwyl u ACNETANE neem nie. Topikale produkte wat sagkens werk kan gebruik word indien dit deur u dokter aanbeveel word.

LET WEL: Dit is belangrik dat u nie vitamien A-aanvullings neem terwyl u op ACNETANE is nie. Maak seker dat enige multivitamiene wat u neem nie vitamien A bevat nie.

- Moenie enige waks-behandeling ondergaan om hare te verwyder terwyl u ACNETANE kapsules neem nie, en vir 6 maande nadat u die behandeling gestaak het.
- ACNETANE maak u vel sensitief vir die son en UV-strale. Moet NIE 'n sonlamp gebruik nie. Vermy die son soveel as moontlik. Dra 'n goeie sonskerm, beskermende klere en 'n hoed wanneer u buite is.
- ACNETANE word geassosieer met ernstige velreaksies. Enige uitslag kan ernstig word. Staak die gebruik van ACNETANE en bel dadelik u dokter indien u konjunktivitis (rooi of ontsteekte oë soos "pienk oog"), 'n veluitslag ontwikkel met koors, blase op bene, arms of gesig en/of sere in u mond, keel, neus, oë, of indien u vel begin afdop.
- ACNETANE kan droë oë veroorsaak. Indien u kontaklense dra, moet u dalk 'n oogsmeermiddel gebruik of u bril dra terwyl u ACNETANE neem.
- ACNETANE kan u nagsig verander. Indien dit gebeur, moenie bestuur of enigiets anders doen wat vereis dat u goed moet sien nie. Raadpleeg ook u dokter. Dit behoort ná die behandeling na normaal terug te keer.
- Moenie bloed skenk terwyl u ACNETANE neem, of vir 30 dae nadat u opgehou het om dit te neem nie. Dit is om die moontlikheid te vermy dat 'n swanger vrou u bloed ontvang wat ACNETANE bevat.
- ACNETANE kan u lewer beïnvloed. Lewerfunksie-toetse moet uitgevoer word voor die aanvang van terapie en een maand na die aanvang van die behandeling. Daarna moet lewerfunksietoetse met drie-maandelikse tussenposes uitgevoer word.
- Daar is gevalle aangemeld van 'n afwyking wat verband hou met hoë druk in die brein. Bel u dokter indien u visuele versteurings, hoofpyn, naarheid en braking ervaar.
- ACNETANE kan lei tot psigose, depressie en selde selfdood-gedrag.
- ACNETANE kan lei tot 'n toename in cholesterolvlakke.
- ACNETANE terapie kan buikpyn, erge diarree of rektale bloeding veroorsaak. Kontak u dokter onmiddellik indien u hierdie simptome ervaar.
- ACNETANE kan skeletafwykings veroorsaak wat verband hou met vergroeisels van been, verharding van spiere en senings, wat styfheid veroorsaak.
- Pasiënte met nierontoereikendheid moet met 'n lae dosis begin word en u dokter kan die dosis verhoog tot die maksimum verdraagbare dosis.
- ACNETANE is spesiaal vir u voorgeskryf. Moet nooit medisyne wat vir u voorgeskryf is met ander deel nie.

Ander medisyne en ACNETANE

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).
Gelyktydige behandeling met tetrasikliene is teenaangedui, aangesien gevalle van nie-kwaadaardige intrakraniale hipertensie aangemeld is. Gelyktydige gebruik met vitamien A, insluitend dieetaanvullings, word nie aanbeveel nie as gevolg van hul bydraende toksiese effekte wat kan lei tot hipervitaminose A.

ACNETANE saam met kos en drank

Neem ACNETANE een of twee keer per dag saam met kos of melk.

Swangerskap, borsvoeding en vrugbaarheid

BELANGRIKE INSTRUKSIES EN WAARSKUWINGS VIR VROULIKE PASIËNTE:
U mag nie ACNETANE neem indien u swanger is of vermoed dat u swanger is, indien u van plan is om swanger te raak, of indien u borsvoed nie.

- **ACNETANE veroorsaak ernstige geboortedefekte. Indien u potensieel vrugbaar is, moet u twee betroubare metodes van voorbehoeding gebruik terwyl u op ACNETANE is, beginnende 'n maand voor die aanvang van ACNETANE terapie en vir tot een maand nadat ACNETANE gestaak is.**
- **ACNETANE terapie moet op die tweede of derde dag van menstruasie begin word. 'n Swangerskapstoets word 2 weke voor die aanvang van die behandeling gedoen, en kan tydens ACNETANE behandeling gedoen word.**
- **Indien u potensieel vrugbaar is, moet u die Toestemmingsvorm onderteken voordat u met ACNETANE terapie begin.**

LET WEL: Indien u wel swanger raak terwyl u ACNETANE neem, is daar 'n hoë risiko vir ernstige geboortedefekte vir u baba.
Neem asseblief kennis dat u dokter die volgende inligting saam met u voorskrif aan u moet gee:

- **Pasiënt Inligtingsbiljet**
- **Brosjure oor Geboortebeperking**
- **Vroulike Pasiëntinligting en Toestemmingsvorm**

Bestuur en gebruik van masjinerie

Minder gereelde newe-effekte soos slaperigheid en visuele versteurings is aangemeld (sien afdeling 4). Indien dit met u gebeur, moet u nie bestuur of masjinerie hanteer nie.
Gevalle van verminderde nagsig het voorgekom tydens ACNETANE terapie en sommige gevalle het ná terapie voortgeduur. Omdat dit skielik kan gebeur, moet u bewus wees van die potensiële probleem en versigtig wees wanneer u bestuur of masjinerie hanteer.
Dit is nie altyd moontlik om te voorspel tot watter mate ACNETANE met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie bestuur of masjinerie hanteer voordat u bewus is van die mate waartoe ACNETANE u beïnvloed nie.

ACNETANE bevat etielparabeen en sojaboonolie

- Ethylparabeen kan allergiese reaksies veroorsaak.
- Indien u allergies is vir grondboontjies of soja, moenie ACNETANE neem nie.

3. Hoe om ACNETANE te neem

- Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
  Gebruik altyd ACNETANE presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.
- Neem ACNETANE een of twee keer per dag, saam met kos of melk.
- Die dosis ACNETANE sal verskil vir verskillende pasiënte. Dit is gebaseer op u liggaamsgewig. U dokter kan later u dosis verander, afhangende van u reaksie en indien newe-effekte voorkom.
  LET WEL: Aknee kan aanvanklik vererger. Moenie ophou om die medisyne te neem nie, want dit is noodsaaklik dat u die behandeling gedurende hierdie fase voortsit.
- Die algemene dosis ACNETANE vir volwassenes en tieners is 0,5 tot 1,0 mg per kg.
- 'n Behandelingskursus duur gewoonlik 16-24 weke, afhangende van die daaglikse dosis. Nadat die behandeling gestaak is, sien baie pasiënte 'n verdere verbetering en is herhaalde kursusse gewoonlik nie nodig nie. Indien 'n definitiewe terugslag wel voorkom, kan 'n herhalingskursus gegee word, maar moet eers ten minste 8 weke na die staking van die eerste kursus begin word.
- U dokter sal u inlig hoe lank u behandeling met ACNETANE sal duur. Moenie die behandeling vroegtydig staak nie, tensy u dokter geraadpleeg is.
- Indien u die indruk kry dat die effek van ACNETANE te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer ACNETANE neem as wat u moes

Akute toksisiteit van ACNETANE is beperk. In geval van oordosis of toevallige inname, raadpleeg egter u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u vergeet om ACNETANE te neem

Indien u 'n dosis gemis het, neem dit so gou as wat u kan. Indien dit egter amper tyd is vir u volgende dosis, slaan die vergete dosis oor en gaan voort soos voorheen. Moenie 'n dubbele dosis neem / ontvang om vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte

ACNETANE kan newe-effekte hê.
Nie alle newe-effekte wat vir ACNETANE aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ACNETANE neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van ACNETANE en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Ernstige (anafilaktiese) reaksies: sukkel met asemhaling of om te sluk, wat veroorsaak word deur skielike swelling van die keel, gesig, lippe en mond. Ook skielike swelling van die hande, voete en enkels.
- Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op ACNETANE gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Indien enige van die volgende gebeur, staak die gebruik van ACNETANE en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Ernstige veluitslag (meervormige eriteem, Stevens-Johnson se sindroom en toksiese epidermale nekrolise), wat potensieel lewensgevaarlik is en onmiddellike mediese hulp benodig. Dit verskyn aanvanklik as sirkelvormige kolle, dikwels met sentrale blase, gewoonlik op arms en hande of bene en voete, meer ernstige veluitslag kan blase op die bors en rug insluit.
- Bykomende simptome soos infeksie van die oog (konjunktivitis) of sere in die mond, keel of neus kan voorkom. Ernstige vorme van veluitslag kan vererger tot wydverspreide afdop van die vel wat

lewensgevaarlik kan wees. Hierdie ernstige veluitslag word dikwels voorafgegaan deur hoofpyn, koors, liggaamspyn (griepagtige simptome).

- Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte

- Bloedarmoede (swakheid, moegheid, bleek vel)
- Meer geneig om infeksies te kry (kom voor as witbloedselle aangetas word)
- Kneusing, bloeding of stolling gebeur makliker (kom voor as stollingselle aangetas word)
- Hoofpyn
- Rooi, geswelde en jeukerige ooglede
- Droë oë, konjunktivitis (Pienk Oog)
- Neusbloeding en droë neus
- Verhoogde lewerensieme (gesien in bloedtoetse)
- Gebarste lippe
- Droogheid, jeukerigheid of korsvorming van die vel
- Afdop van vel op handpalms of voetsole
- Rooi of pienk veluitslag
- Vel broosheid
- Gewrigspyn, rugpyn of spierpyn
- Veranderde vlakke van vette in die bloed (insluitend HDL of trigliseriede)
- Verminderde hoëdigtheid lipoproteïen
- Verhoogde bloedsuiker
- Bloed in urien
- Proteïen in urien

Minder gereelde newe-effekte

- Geswelde limfknope
- Oormatige dors; gereelde behoefte om te urineer; bloedtoetse toon 'n toename in u bloedsuiker. Hierdie kan alles tekens van diabetes wees.
- Hoë kalsium in urien
- Depressie
- Aggressiewe neigings
- Angs
- Gemoedsverandering

- Selfdoodgedagtes of selfdoodpoging
- Hoofpyn met visuele versteurings
- Stuipaanvalle
- Lomerigheid (slaperigheid)
- Vae of dowwe visie
- Verminderde nagsig
- Kleurblindheid
- Dowwe oppervlak op die oog
- Sensitiwiteit van oë vir lig
- Swak gehoor
- Inflammasie van bloedvate
- Hygende asemhaling of hoes
- Heesheid (stemverandering)
- Erge maagpyn, bloederige diarree, naarheid of braking
- Vergeling van die oë of vel
- Haarverlies
- Oormatige gesig-, bors- en rughare by vroue
- Ernstige of verergerde aknee
- Inflammasie en abnormale veranderinge aan die naels
- Rooiheid van die gesig of wange
- Sensitiwiteit van die vel vir hitte
- Verdonkering van areas op die vel
- Verhoogde sweet
- Toename van klein, rooi, "keisteen-agtige" knoppe op die vel
- Voel oor die algemeen onwel, of gevoel van ongemak
- Bakteriële infeksie

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld

via die vorm "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ACNETANE te verskaf.
Daarbenewens kan vermoedelike nadelige reaksies via Adcock.AEReports@adcock.com by die Houer van Sertifikaat van Registrasie aangemeld word.

5. Hoe om ACNETANE te bêre

BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS
Bêre teen of benede 25 °C, beskerm teen lig en vogtigheid.
Moenie uit die buitenste houer verwyder voordat dit nodig is vir gebruik nie.
Neem vervalde, onbekende of ongebruikte medisyne terug na u apteker vir vernietiging.
Moenie in 'n badkamer bêre nie.
Moenie gebruik ná die vervaldatum wat op die etiket vermeld word nie.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Die aktiewe bestanddeel in elke ACNETANE 10 mg kapsule is 10 mg isotretinoïen.
Die aktiewe bestanddeel in elke ACNETANE 20 mg kapsule is 20 mg isotretinoïen.

Die ander bestanddele is
Kapsule-vulsel:
Gebutileerde Hidroksianisool
Dinatriumedetaat
Wit waks
Sojaboonolie
Kapsule-dop:
Amarant (CI 16185)
Helder Blou (CI 42090)
Etielparabeen
Gelatien
Gliserien
Poliëtileenglikol 400
Titaandioksied

Hoe ACNETANE lyk en inhoud van die verpakking

10 mg Kapsules: Pienk ovaalvormige sagte gelatienkapsule wat 'n geel olierige suspensie bevat, beskikbaar in stulpverpakkings wat 60 kapsules bevat.
20 mg Kapsules: Pers ovaalvormige sagte gelatienkapsule wat 'n geel olierige suspensie bevat, beskikbaar in stulpverpakkings wat 60 kapsules bevat.

Houer van Sertifikaat van Registrasie

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Qingpu-distrik,
Sjanghai
Volksrepubliek van Sjina

Hierdie biljet is mees onlangs hersien op

10 Oktober 2024

Registrasienommer(s)

10 mg Kapsules:	34/13.4.2/0356
20 mg Kapsules:	34/13.4.2/0357

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

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

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

adcock ingram

10 Oktober 2024