Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: NEOTIGASON 10 mg and 25 mg
Date of Registration: 5/10/1995	Dosage form & strength: 10 mg and 25 mg acitretin capsules

PATIENT INFORMATION LEAFLET:

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SCHEDULING STATUS:

S5

NEOTIGASON® 10 mg (capsules)

NEOTIGASON® 25 mg (capsules)

Contains sugar (glucose 410 mg)

Read all of this leaflet carefully before you start taking NEOTIGASON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

NEOTIGASON 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 NEOTIGASON IS AND WHAT IT IS USED FOR**
2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEOTIGASON**
3. **HOW TO TAKE NEOTIGASON**
4. **POSSIBLE SIDE EFFECTS**
5. **HOW TO STORE NEOTIGASON**
6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

1. WHAT NEOTIGASON IS AND WHAT IT IS USED FOR:

NEOTIGASON contains a medicine called acitretin. Acitretin belongs to a group of medicines known as retinoids which are used to treat skin problems.

NEOTIGASON is used to treat severe skin problems characterised by the thickening and shedding of the skin, such as psoriasis, ichthyosis and Darier's disease, and which does not respond to other conventional treatments satisfactorily. It works by making your skin grow more normally.

The use of NEOTIGASON must be supervised by a dermatologist (a doctor who specialises in the treatment of skin problems).

To help you get the full benefits from NEOTIGASON you should read this leaflet carefully and ask your dermatologist to explain anything you do not understand.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEOTIGASON:

Do not take NEOTIGASON:

- If you are allergic (hypersensitive) to acitretin, glucose or any of the other ingredients of NEOTIGASON (see **section 6**).
- If you are pregnant or think you may be pregnant, or if you are a girl or woman of childbearing age and could therefore become pregnant because NEOTIGASON can cause malformations in the unborn baby. If you have discussed the possible risks with the doctor and nevertheless

decide to use NEOTIGASON, you must STRICTLY follow a number of instructions (see **Pregnancy, breastfeeding and fertility**).

- If you are breastfeeding.
- If you have liver or kidney disease.
- If you are taking antibiotics called tetracyclines (used to treat infections).
- If you have very high fat (cholesterol) levels in your blood.
- If you are taking other preparations with high levels of Vitamin A.
- If you use the so-called mini-pill (a contraceptive pill with only a low progesterone content).
- In children, unless the doctor considers it necessary.
- Make sure your doctor knows if you are taking methotrexate (another medicine used to treat skin problems).

Warnings and precautions:

Take special care with NEOTIGASON:

Make sure your doctor knows if:

- You, or members of your family, have a history of heart problems or high triglyceride (a fat-like substance) or cholesterol levels in the blood. Your doctor may wish to do some blood tests to check your liver and blood before and during treatment. NEOTIGASON increases blood fats, such as cholesterol or triglycerides which have been associated with pancreatitis. Tell your doctor if you experience severe pain in the abdomen and back (these can be signs of inflammation of the pancreas).
- You, or members of your family have diabetes mellitus (sugar diabetes). NEOTIGASON may disturb your blood sugar levels, so you should test this more frequently during treatment and tell your doctor if it goes outside your normal range.
- You drink a lot of alcohol.

  NEOTIGASON may increase blood levels of fat-like substances in some patients. Because of this, you should not drink alcoholic drinks or at least reduce the amount you normally drink while taking NEOTIGASON. If your doctor finds that you have high levels of triglycerides or cholesterol while taking this medicine, you may need to go on a low-fat diet. Women of

childbearing age must not consume alcohol (in drinks, food or medicines) during treatment with NEOTIGASON and for 2 months after stopping NEOTIGASON therapy (see **Taking NEOTIGASON with food, drink and alcohol**).

- Do not take more than the recommended daily dietary allowance of vitamin A per day (i.e. 4 000 to 5 000 (IU) International Units). If you take vitamins check the label to see how much vitamin A they contain. If you are not sure, ask your doctor or pharmacist.
- Make sure your doctor knows if you are taking phenytoin (a medicine used to treat epilepsy).
- You may become more sensitive to sunlight while taking this medicine. Avoid too much sun and do not use a sunlamp. Before going out into strong sunlight apply a sunblock (at least SPF 15) to exposed skin.
- Your night vision may be affected by this medicine, and you may develop dry eyes or sight problems. If this happens, tell your doctor so your vison can be monitored. Always be cautious when driving or operating machinery at night.
- Rarely ulcers can develop on the eye. If you have eye pain (sometimes with sensitivity to light or blurred vision), consult your doctor immediately to investigate and treat your symptoms.
- If you wear contact lenses. NEOTIGASON causes dry eyes therefore you may have to wear glasses throughout the period of treatment or use lubricants for your eye such as artificial tears.
- NEOTIGASON should not be given to children since it may cause changes in bone growth in children (see **Do not take NEOTIGASON**)
- You have ever had any mental health problems including depression, irritability, aggressive tendencies, mood changes or signs of psychosis (altered sense of reality, such as hearing voices or seeing things that are not there). This is because taking NEOTIGASON may affect your mood. 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 NEOTIGASON could affect your mood and behaviour. They may notice these changes and help you identify any problems that you need to talk to your doctor about.
- A serious condition which causes the small blood vessels (capillaries) to leak has been reported very rarely (Capillary Leak Syndrome/Retinoic Acid Syndrome). This can lead to severe hypotension (low blood pressure), oedema (build-up of fluid leading to swelling) and

shock (collapse). Inform your doctor immediately if you experience these symptoms (see **POSSIBLE SIDE EFFECTS**).

- A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (exfoliative dermatitis) has been reported very rarely. Inform your doctor immediately if you experience these symptoms (see **POSSIBLE SIDE EFFECTS**).
- NEOTIGASON may cause increased pressure in the head. You should tell your doctor if you experience severe headaches, feeling or being sick or changes in sight. Your doctor may carry out further checks.
- NEOTIGASON can cause changes in bone growth. You should tell your doctor if you feel pain in your muscles or bones. Your doctor may carry out further checks.
- You should inform your doctor if you experience hair loss which is a very common side effect of NEOTIGASON (see **POSSIBLE SIDE EFFECTS**).

Special note for blood donors:

- You should not donate blood either during or for at least three years after NEOTIGASON treatment.
- You must not receive donor blood from patients treated with NEOTIGASON if you are a woman of childbearing age.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before taking NEOTIGASON.

Children and adolescents:

Children and adolescents younger than 18 years should not take NEOTIGASON.

Other medicines and NEOTIGASON:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please inform your doctor if you are taking any of the following medicines:

- medicines or vitamin supplements that contain Vitamin A
- phenytoin (a medicine used to treat epilepsy)
- methotrexate (a medicine used in the treatment of skin problems, arthritis or cancer)
- tetracycline antibiotics (used to treat infections)
- other retinoid medicines such as isotretinoin (used to treat acne)
- low dose progesterone only contraceptives (minipills), since NEOTIGASON may reduce their contraceptive effect, therefore you must not use these pills as a contraceptive together with NEOTIGASON.

NEOTIGASON with food, drink and alcohol:

Take NEOTIGASON with food or milk once a day.

You should not drink alcohol during treatment with NEOTIGASON as the risk for side effects would be increased. Girls and women of childbearing age **must not** consume alcohol (in drinks, food or medicines) at all during treatment with NEOTIGASON and 2 months after stopping it (see **Pregnancy, breastfeeding and fertility**).

Taking NEOTIGASON together with alcohol may result in the formation of a compound (etretinate), which may be harmful to an unborn child, and if formed takes some time for it to be totally removed from the body.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking

NEOTIGASON.

Pregnancy:

NEOTIGASON must NOT be taken during pregnancy.

IMPORTANT:

NEOTIGASON will damage an unborn baby.

Female patients must strictly follow these instructions.

- You must not take NEOTIGASON if you are pregnant or think you may be pregnant.
- You must use an effective method of birth control for one month before NEOTIGASON treatment, during treatment and for three years after treatment ends. Before you start NEOTIGASON treatment, your doctor should ask you to take a pregnancy test, which must be negative. You should start taking NEOTIGASON on the second or third day of your menstrual cycle.
- You must not become pregnant at any time during NEOTIGASON treatment or for three years after treatment ends.
- Contact your dermatologist immediately if you do become pregnant or think you may be pregnant during NEOTIGASON treatment or in the three years after NEOTIGASON treatment ends.
- You must not take NEOTIGASON if you are breastfeeding. NEOTIGASON is likely to pass into your breastmilk and may harm your baby.

Women who might become pregnant are prescribed NEOTIGASON only 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 be able to understand why you must not get pregnant and what you need to do to prevent getting pregnant.
- You must be able to adequately take precautions to prevent a pregnancy.
- You must have talked about contraception (birth control) with your doctor. The doctor will give

you information on how not to get pregnant. The doctor may send you to a specialist for contraception advice.

Women must use effective contraception before, during and after taking NEOTIGASON.

- You must use an effective method of birth control for at least 1 month before you start taking NEOTIGASON and for 3 years after stopping NEOTIGASON treatment.
- You will be advised to use a combination of 2 methods (a birth control pill or intra-uterine device combined with a condom or diaphragm also known as a cap).
- You must use contraception even if you do not have periods or you are not sexually active or if you have a history of infertility (unless you doctor decides this is not necessary).
- You must start NEOTIGASON treatment on the second or third day after your next normal menstrual period.

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

- At least 3 days before you start NEOTIGASON treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with NEOTIGASON.
- You must agree to regular follow-up visits, ideally every month.
- You must agree to have regular pregnancy tests, ideally every month during NEOTIGASON treatment (because some medicine may still be left in your body), and every 1 to 3 months for 3 years after stopping NEOTIGASON (unless your doctor decides this is not necessary in your case).
- You must agree to extra pregnancy tests if your doctor asks you.
- You must not get pregnant during NEOTIGASON treatment or for 3 years afterwards because some medicine may still be left in your body.

Additional precautions:

- You must follow these precautions again during any repeat treatment with NEOTIGASON.
- You must not consume any alcohol (in drinks, food or medicines) while you are taking

NEOTIGASON and for 2 months after stopping it, because alcohol can increase the risk of malformations.

- You should not donate blood during NEOTIGASON treatment and for 3 years after stopping NEOTIGASON because an unborn baby could be harmed if a pregnant patient receives your blood.
- You should not receive donor blood from patients treated with NEOTIGASON.

If you get pregnant while taking NEOTIGASON, stop taking the medicine immediately, and contact your doctor. Your doctor may send you to a specialist for advice.

Breastfeeding:

Do not take NEOTIGASON if you are breastfeeding your baby.

Advice for men:

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

Driving and using machines:

Your vision may be affected, particularly at night, while you are taking NEOTIGASON treatment. Be careful if you are driving or using any tools or machines.

It is not always possible to predict to what extent NEOTIGASON may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NEOTIGASON affects them.

NEOTIGASON contains glucose:

NEOTIGASON contains glucose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking NEOTIGASON.

3. HOW TO TAKE NEOTIGASON:

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

Always take NEOTIGASON exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Always take the capsules as your doctor tells you to.
- Take NEOTIGASON at a mealtime, preferably with a drink of milk.
- Your doctor will tell you how much medicine to take. The usual starting dose is 25 mg (one 25 mg capsule) or 30 mg (three 10 mg capsules) a day although lower starting doses are sometimes required. After 2 to 4 weeks your doctor may change the dose. This will depend on how well you are getting on with your medicine.
- You will usually be on a dose of between 25 mg to 50 mg a day for another six to eight weeks. However, higher doses or longer treatment times up to 6 months are sometimes needed. Normally, you should not take more than 75 mg (three 25 mg capsules) per day.
- NEOTIGASON should not be given to children (see **Do not take NEOTIGASON**). If it is given to a child, the doctor will decide the correct dose. This is based on the child's weight.
- The capsules should be taken once a day with a meal, or with some milk. Swallow the capsules whole, do not suck or chew them.
- If you are a woman of childbearing age, you should have been using an effective method of contraception for at least 1 month prior to starting NEOTIGASON. It is recommended that you perform a pregnancy test every month to confirm that you are not pregnant. You should start taking NEOTIGASON on the second or third day of your menstrual cycle (see **Pregnancy, breastfeeding and fertility**).

Your doctor will tell you how long your treatment with NEOTIGASON will last. Do not stop treatment early because you feel better. If you have the impression that the effect of NEOTIGASON is too strong or too weak, tell your doctor or pharmacist.

If you take more NEOTIGASON than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the

nearest hospital or poison centre.

If forget to take NEOTIGASON:

If you miss a dose, take it as soon as possible. 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 to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

NEOTIGASON can have side effects.

Not all side effects reported for NEOTIGASON are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking NEOTIGASON, please consult your healthcare provider for advice.

You will probably have some unwanted reactions to your treatment, even before you see your skin getting better. These effects often wear off as your treatment continues and your doctor can help you to deal with them.

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

- skin rash, swelling or itching of the skin, swelling of the face, lips, throat or tongue, red and swollen eyes, severe nasal congestion, asthma or wheezing
- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems
- severe headache, feeling or being sick or problems with your eyesight.

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

- aches and pains in your muscles, bones or joints. This may mean you have extra growth on the surface of your bones. This can happen if you take NEOTIGASON for a long time.
- swelling of your hands, feet or ankles.

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:

- dry, irritated or swollen eyes, which may lead to intolerance of contact lenses
- dry, irritated or runny nose, nose bleeding
- dry mouth, thirst
- dryness or inflammation of the lips, which may be alleviated by application of a fatty ointment
- itchy skin, hair loss, acne, peeling of the skin especially on the palms and soles of your feet or even the rest of your body
- changes in how the liver is working (shown by blood tests)
- increased levels of fats (cholesterol) in your blood (shown by blood tests)
- inflammation (swelling) inside the mouth, stomach pain, diarrhoea, feeling or being sick
- fragile skin, sticky feeling on the skin or a rash, skin inflammation, changes to the texture of the hair, brittle nails, skin infection around a nail, redness of the skin.

Less frequent side effects:

- dizziness
- blurred vision
- inflammation (swelling) of the gums
- inflammation of the liver
- fissures, cracks or fine linear scars in the skin e.g. around the mouth (rhagades), blisters and inflammation of the skin (dermatitis bullous), skin being more sensitive to the sun (photosensitivity reaction)
- damage to the peripheral nervous system, which may include symptoms such as muscle weakness, numbness and tingling in the feet and hands or burning, stabbing or shooting pain

- night blindness.

Side effects with unknown frequency:

- altered mood, signs of psychosis: altered sense of reality, such as hearing voices or seeing things that are not there
- infection of the vagina (also known as candida or thrush)
- impaired hearing, ringing in the ear (tinnitus)
- a serious condition which causes the small blood vessels (capillaries) to leak (Capillary Leak Syndrome/Retinoic Acid Syndrome), which can lead to severe hypotension (low blood pressure), oedema (build-up of fluid leading to, swelling) and shock (collapse)
- flushing (sweating, skin redness on the face)
- changes in the sound of the voice (dysphonia)
- changes in the way things taste, bleeding in the rectum (anus)
- a serious skin reaction with symptoms such as rash, blistering or peeling of the skin (exfoliative dermatitis), small, reddish bumps or nodules on the skin that may bleed easily (pyogenic granuloma), dryness and scaling or thinning of the skin especially on the face, thinning hair, sweating
- cracks or scaring at the corners of the mouth, loss of eyelashes or eyebrows (madarosis)
- general unwell feeling, drowsiness
- improved or worsened glucose tolerance in diabetic patients.

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

5. HOW TO STORE NEOTIGASON:

Store below 25 °C. Protect from moisture.

Store all medicines out of reach of children.

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

Return unused or expired medicines to your pharmacist for safe disposal.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What NEOTIGASON contains:

The active substance is acitretin.

Each capsule contains 10 mg or 25 mg acitretin.

The other ingredients are:

Capsule contents: microcrystalline cellulose, gelatin, glucose, sodium ascorbate.

Capsule shell: gelatin, iron oxide black (E172), iron oxide yellow (E172), iron oxide red (E172), titanium dioxide (E171), shellac, propylene glycol and ammonium hydroxide.

What NEOTIGASON looks like and contents of the pack:

NEOTIGASON 10 mg: capsules with a white, opaque body and brown, opaque cap, imprinted ‘10’ in black.

NEOTIGASON 25 mg: capsules with a yellow, opaque body and brown, opaque cap, imprinted ‘25’ in black.

NEOTIGASON capsules are available in:

NEOTIGASON 10 mg: Pack size 30.

NEOTIGASON 25 mg: Pack size 30.

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: NEOTIGASON 10 mg and 25 mg
Date of Registration: 5/10/1995	Dosage form & strength: 10 mg and 25 mg acitretin capsules

Holder of Certificate of Registration:

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