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

Keep this leaflet. You may need to read it again, or to pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or if you notice that you have problems with blood, liver, kidneys, eyes, bones, joints or muscles, restricted mobility, you must not use these pills anymore.

Girls and women of childbearing age
do not drink alcohol at all during treatment with Acitretin and 2 months after stopping it. Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You must not take Acitretin if you are pregnant. If you get pregnant during treatment with this medicine in spite of the described precautions (See "Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)"

You must be able to understand what may happen if you do not take this medicine properly.

Girls and women of childbearing age must not drink alcohol at all during treatment with Acitretin and 2 months after stopping it. Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You must not take Acitretin if you are pregnant. If you get pregnant during treatment with this medicine in spite of the described precautions (See "Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)"

You must be able to understand what may happen if you do not take this medicine properly.

Girls and women of childbearing age must not drink alcohol at all during treatment with Acitretin and 2 months after stopping it. Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You must not take Acitretin if you are pregnant. If you get pregnant during treatment with this medicine in spite of the described precautions (See "Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)"

You must be able to understand what may happen if you do not take this medicine properly.

Girls and women of childbearing age must not drink alcohol at all during treatment with Acitretin and 2 months after stopping it. Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You must not take Acitretin if you are pregnant. If you get pregnant during treatment with this medicine in spite of the described precautions (See "Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)"

You must be able to understand what may happen if you do not take this medicine properly.

Girls and women of childbearing age must not drink alcohol at all during treatment with Acitretin and 2 months after stopping it. Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
You must not take Acitretin if you are pregnant. If you get pregnant during treatment with this medicine in spite of the described precautions (See "Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)"

You must be able to understand what may happen if you do not take this medicine properly.

Girls and women of childbearing age must not drink alcohol at all during treatment with Acitretin and 2 months after stopping it. Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)

Other medicines and Acitretin
Tell your doctor or pharmacist if you are taking any other medicines (including any obtained without a prescription). This includes vitamins and herbal medicines as well as other medicines that you can buy over-the-counter. The combination can cause inflammation of the arteries (vasculitis), because this medicine can lower the blood pressure and cause swelling (oedema) and shock (collapse).

If you use a combination of 2 methods (a birth control pill and another method) combined with a condom or diaphragm, your pregnancy test text within 3 days before starting treatment and the test must indicate that you are not pregnant.

You must start treatment on the second or third day after your next normal period.

- You must be adequately informed to undergo a pregnancy test every month of treatment.
- You must test yourself every day for at least 3 days of your next period.
- If you are menstruating, you must consume any alcohol (in drinks, food or medicines) while you are taking Acitretin and for 3 months after stopping it. Also your doctor should have your blood tested for at least 3 months after stopping it.
- You must not start treatment on the second or third day after your next normal period.
- You must talk to your doctor if any of the following signs of bone changes: pain in bones, joints or muscles, restricted mobility, you must undergo a pregnancy test within at least 3 months after stopping Acitretin.
- This test must indicate that you are not pregnant. You will be advised about the precautions (See "Only under STRICT conditions can Acitretin be prescribed to women who might become pregnant, because of the risk for congenital malformations (harmful effects on the unborn baby)"

- you must suffer from a severe disorder that does not allow any improvement with other treatments.
- you must be able to understand the instructions provided by your doctor and the possible side-effects of the medicine.
- your doctor has explained the risks of becoming pregnant during treatment and for 3 years after stopping it. Also your doctor should have your blood tested for at least 3 months after stopping it.
- you must be able to understand what may happen if you do not take this medicine properly.
- you must be able to understand what may happen if you do not take this medicine properly.
- you must be able to understand what may happen if you do not take this medicine properly.
- you must be able to understand what may happen if you do not take this medicine properly.
3 How to take Acitretin

Always take Acitretin exactly as your doctor tells you. Check with your doctor or pharmacist if you are not sure.

• Take Acitretin at a meal time, preferably with a drink of water.

If you forget taking Acitretin

• If you have any further questions on the use of this medicine and consult your pharmacist or nurse. This includes any possible side effects you experience.

4 How to use Acitretin

What Acitretin contains


Other side effects observed during treatment with Acitretin

Symptoms can include severe headache, vision, impaired night vision. Wearing of glasses may be required.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects you experience.

What Acitretin looks like and contents of the pack

Acitretin 10 mg capsules consist of a white to off-white tablet and a brown printed black with “A10” on the capsule body and filled with yellow powder. Acitretin 25 mg capsules consist of a yellow to light yellow and a brown printed black with “A30” on the capsule body and filled with yellow powder. The capsules are packaged in PVC/PVDC aluminium blister packs. Pack sizes: 30 and 60 hard capsules. Not all pack sizes may be marketed.

PLC

Acitretine CF 10 and 25 mg capsules NL Acitretine CF 10 and 25 mg capsules Marketing Authorisation Holder and Manufacturer

Gena.

Manufactured in the United Kingdom by Rösch Healthcare Ltd, RTH, UK. This medicinal product is authorised in the Member States of the EEA under the following names:

What Acitretin looks like and contents of the pack

Acitretin 10 mg capsule consists of a white to off-white tablet and a brown printed black with “A10” on the capsule body and filled with yellow powder. Acitretin 25 mg capsules consist of a yellow to light yellow and a brown printed black with “A30” on the capsule body and filled with yellow powder. The capsules are packaged in PVC/PVDC aluminium blister packs. Pack sizes: 30 and 60 hard capsules. Not all pack sizes may be marketed.

PLC

Acitretine CF 10 and 25 mg capsules NL Acitretine CF 10 and 25 mg capsules Marketing Authorisation Holder and Manufacturer

Gena.

Manufactured in the United Kingdom by Rösch Healthcare Ltd, RTH, UK. This medicinal product is authorised in the Member States of the EEA under the following names: