Package leaflet: Information for the user

Triregol coated tablets

levonorgestrel/ethinylestradiol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Triregol is and what it is used for

Triregol is a combined oral contraceptive, one of a group of drugs often referred to as the Pill. The Pill provides a reliable, reversible method of contraception. Triregol contains two types of hormone: an oestrogen, ethinylestradiol, and a progestogen, levonorgestrel. It is a triphasic contraceptive. This means that there are three levels of hormones in each pack which reflect the changing levels in your normal menstrual cycle. These hormones stop the ovary from releasing an egg each month. They also thicken the mucus at the neck of the womb making it more difficult for the sperm to reach the egg, and alter the lining of the womb to make it less likely to accept a fertilised egg.

Remember:
- Triregol needs to be taken as directed to prevent pregnancy
- Combined oral contraceptive pills like Triregol will not protect you against sexually transmitted diseases (such as AIDS). Only condoms can do this.

2. What you need to know before you take Triregol

Do not take Triregol
- if you are allergic to levonorgestrel, ethinylestradiol or any of the other ingredients of this medicine (listed in section 6);
- you have ever had a disorder affecting your blood circulation known as thrombosis (for example, blood clots in your legs, lungs, heart, brain, eyes or in any other part of your body);
- you have ever had a heart attack or angina (severe chest pain) or a stroke;
- you or any member of your close family have any medical condition which makes you more at risk of developing blood clots (see also the section 'The pill and thrombosis');
- you have diabetes with changes to the blood vessels;
- you have or have ever had disorder of blood vessels in the eye;
- you have severe high blood pressure;
- you have any heart and/or vessel disorders, such as irregular heart rhythm or a heart valve disease;
- you have liver disease or if you have ever had this;
- you have liver tumours or if you have ever had these;

- you have breast cancer or other cancer, for example ovarian cancer, cervical cancer, or cancer of the uterus (womb);
- you have unusual bleeding from your vagina;
- you have or have ever had migraine;
- you are pregnant or think you might be.

Do not use Triregol if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir (see also in section "Other medicines and Triregol").

If you get any of these conditions while you are taking Triregol, do not take any more pills and contact your doctor immediately. In the meantime, use another method of contraception such as a condom or cap plus spermicide.

Warnings and precautions
Talk to your doctor or pharmacist before taking Triregol.

Regular check-ups
Before you start taking Triregol, your doctor should take your medical history by asking you some questions about yourself and other members of your family. Your doctor will take your blood pressure and make sure you are not pregnant. Your doctor may also check your breasts, abdomen and pelvic organs. Once you have started taking Triregol, your doctor will see you again for regular check-ups. This will happen when you go back to your doctor for more pills.

Tell your doctor if any of the following conditions apply to you.
If the condition develops or gets worse while you use Triregol, you should also tell your doctor. Also, do not take any more pills until you have spoken to your doctor. In the meantime, use another method of contraception such as a condom or cap plus spermicide.

- If you get a migraine for the first time, or if you already have migraines but they get worse or happen more often than before.
- You develop symptoms of a blood-clot formation. (See also the section - 'The pill and thrombosis.') These symptoms include:
    - unusual pain or swelling in your legs;
    - sudden sharp pains in your chest which may reach your left arm;
    - sudden shortness of breath or difficulty in breathing;
    - sudden coughing for no apparent reason;
    - any unusual, severe or long-lasting headache;
    - any sudden changes to your eyesight (such as loss of vision or blurred vision);
    - slurred speech or any other difficulties affecting your speech;
    - vertigo (spinning sensation);
    - dizziness, fainting or fits;
    - sudden weakness or numbness in one side or part of your body;
    - difficulties in moving around (known as motor disturbances); or
    - severe pain in your abdomen (known as acute abdomen).
- You require surgery or become immobilised (not being able to move around as normal), since this may increase the risk of blood-clot formation. You should stop taking Triregol at least four weeks before a planned major operation (for example, stomach surgery), or if you are having any surgery to your legs. Also, if you are immobilised for a long time (for example, you are in bed after an accident or operation, or you have a plaster cast on a broken leg). Your doctor will tell you when you can start taking Triregol again.
- If you become or think you may have become pregnant.

<u>Signs of a blood clot:</u>
- a migraine for the first time, a migraine that is worse than normal, or unusually frequent or severe headaches
- any sudden changes to your eyesight (such as loss of vision or blurred vision)
- any sudden changes to your hearing, speech, sense of smell, taste or touch

- pain or swelling in your leg
- stabbing pain when you breathe
- coughing for no apparent reason
- pain and tightness in the chest
- sudden weakness or numbness in one side or part of your body
- dizziness or fainting.

Signs of a severe allergic reaction or worsening of hereditary angioedema:
- **if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately**. Products containing estrogens may cause or worsen the symptoms of hereditary and aquired angioedema.

Signs of breast cancer include:
- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel.

Signs of cancer of the cervix include:
- vaginal discharge that smells and/or contains blood
- unusual vaginal bleeding
- pelvic pain

Signs of severe liver problems include:
- severe pain in your upper abdomen
- yellow skin or eyes (jaundice)
- inflammation of the liver (hepatitis)
- your whole body starts itching.

If you think you may have any of these, see a doctor straight away. You may need to stop taking Triregol.

Tell your doctor before starting to take Triregol if
you know you suffer from any of the following conditions. You need to tell your doctor if this is the case as these conditions may get worse while you are taking the pill. If any of these conditions do get worse or you have them for the first time, tell your doctor as soon as you can. Your doctor may tell you to stop using Triregol and advise you to use another method of contraception:
- If you, or any member of your family, have a blood-fat (lipid) disorder called hypertriglyceridaemia, as this disorder can increase your risk of getting a disease of your pancreas, called pancreatitis.
- If you suffer from:
  - high blood pressure (hypertension);
  - yellowing of the skin (jaundice);
  - itching of your whole body (pruritus);
  - gallstones;
  - the inherited disease called porphyria;
  - systemic lupus erythematosus - SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs);
  - a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail);
  - the movement disorder called Sydenham's chorea;
  - the rash known as herpes gestationis;
  - the inherited form of deafness known as otosclerosis;
  - disturbed liver function;
  - diabetes;
  - depression or mood changes;
  - Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases);

- brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps.

Bleeding between periods should not last long
A few women have a little unexpected bleeding or spotting while they are taking Triregol, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Triregol as usual. The problem should disappear after the first few strips.
You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

Make an appointment to see your doctor if you get breakthrough bleeding or spotting that:
- carries on for more than the first few months
- starts after you've been taking Triregol for a while
- carries on even after you've stopped taking Triregol.

The pill and thrombosis
Some studies have suggested that the risk of developing various blood-circulation disorders is slightly greater in women who take the combined pill than in those who do not. This can lead to a thrombosis. A thrombosis is when you have a blood clot which may block a blood vessel. The clot may form in the veins (venous thrombosis) or in the arteries (arterial thrombosis). Most blood clots can be treated, with no long-term danger. However, a thrombosis can cause serious permanent disabilities or could even kill you, though this is very rare.

Blood clots sometimes form in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a 'pulmonary embolism'.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

In extremely rare cases, blood clots can form in other places such as the liver, gut, kidney or eye.

A blood clot can develop whether or not you are taking the pill. It can also happen if you become pregnant. The risk is higher in people who take the pill than in people who don't take the pill, but it isn't as high as the risk during pregnancy. A thrombosis is most likely in the first year of taking any combined pill.

In healthy women who are not pregnant and not taking the pill, there are about 5 to 10 cases of thrombosis for every 100000 women each year.

In women taking the pill with a low-oestrogen content, there are about 40 cases of thrombosis for every 100000 women each year.

In pregnant women, there are about 60 cases of thrombosis for every 100000 pregnancies each year.
Symptoms of a blood-clot formation are listed under 'Tell your doctor immediately if'.
If you notice possible signs of a thrombosis, stop taking the pill and contact your doctor immediately. In the meantime, use another method of contraception such as a condom or cap plus spermicide.

You should also remember that certain conditions can increase your risk of thrombosis. They include:
- age (the risk of having a heart attack or stroke increases as you get older);
- smoking (with heavier smoking and increasing age, your risk of thrombosis increases).**When using the pill stop smoking, especially if you are over 35;**
- being very overweight (obese);
- having disorder of blood fat (dyslipoproteinemia);

- high blood pressure;
- if you suffer from migraines;
- if you have a heart valve disease or a particular type of irregular heartbeat (atrial fibrillation).

The pill and cancer
Some studies have found that you may have an increased risk of cervical cancer if you use the pill in the long term. This increased risk may not be caused by the pill itself, but could be due to effects of sexual behaviour and other circumstances. More frequent check-ups may increase the rate of detection of cervical cancer.
Every woman is at risk of breast cancer whether or not she takes the pill. Breast cancer is rare in women under 40. Breast cancer has been found slightly more often in women who take the pill than in women of the same age who don't take the pill. If you stop taking the pill, this reduces your risk, so that 10 years after stopping the pill the risk of finding breast cancer is the same as for women who have never taken the pill. Breast cancer seems less likely to have got worse when it has been found in women who take the pill, than it is in women who do not take the pill.
Rarely, using the pill has led to liver diseases and benign liver tumours. Very rarely, the pill has been associated with some forms of malignant liver tumours (cancer) in long-term users. Liver tumours may lead to life-threatening bleeding in the abdomen. So, if you have pain in your upper abdomen that does not soon clear up, tell your doctor. Also, if your skin becomes yellow, you must tell your doctor, as this may be a sign that your liver is not working properly.

Psychiatric disorders
Some women using hormonal contraceptives including Triregol have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Other medicines and Triregol
Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines.

Do not use Triregol if you have Hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).
Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.
Triregol can be restarted approximately 2 weeks after completion of this treatment. See section “Do not take Triregol”.

Some medicines may stop Triregol from working properly.
If you are taking any other medicine while you are taking Triregol, be sure to tell your doctor (or dentist, if they have prescribed antibiotics). Your doctor (or dentist) can tell you whether you should use extra contraceptive precautions and for how long.

Medicines which can sometimes stop Triregol from working properly are:
- antibiotics (such as ampicillin, tetracycline and rifampicin);
- medicines used to treat epilepsy or other illnesses, such as primidone, carbamazepine, oxcarbazepine, topiramate, hydantoins or barbiturates (such as phenobarbitone);
- ritonavir (a medicine used to treat HIV infections);
- griseofulvin (a medicine used to treat fungal infections);
- certain medicines used to treat depression (tricyclic anti-depressants);
- cyclosporine (a suppressor of the immune system used e.g. during transplantation and in rheumatoid arthritis);
- the herbal remedy commonly known as St John's Wort (*Hypericum perforatum*).

You may have to use another method of contraception as well, such as the condom, while you are taking these medicines - and up to 28 days afterwards. Your doctor may advise you to use these extra precautions for even longer.

If you are taking antibiotics, always ask your doctor's advice about extra precautions. Always mention you are on the combined pill if you are prescribed any medicines.
Taking oral contraceptives together with troleandromycin may increase the risk of certain biliary diseases. Oral contraceptives may decrease the plasma concentrations of lamotrigine.
Consult your doctor if you are taking any other medicines while using Triregol.

Before you have any blood tests
Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

Triregol with food and drink
There are no special instructions about food and drink while using Triregol.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you think you might be pregnant, stop taking Triregol and talk to your doctor immediately. Until you have spoken to your doctor, use another method of contraception such as a condom or a cap plus spermicide.

Triregol should not be taken during breast-feeding.

Driving and using machines
Triregol is unlikely to have any effect on the ability to drive and use machines.

Triregol contains lactose, sucrose and sodium
Each tablet contains 31,35 mg of lactose (as lactose monohydrate) and 22 mg of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Triregol

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

This pack is designed to help you remember to take your pills.

Starting the first pack
Take the first pill on the first day of your period. This is day one of your cycle - the day when bleeding starts.
If you start on day 2-5 of your period, you should use another method of contraception as well, such as the condom, for the first seven pill-taking days, but this is only for the first pack.

You can take your pill at any time, but you should take it about the same time each day. You may find it easiest to take it either last thing at night or first thing in the morning. Take a pill every day in the order shown until you finish all 21 pills in the pack.

Once you have taken all 21 pills, stop for seven days. You will probably bleed during some of these seven days.

You do not need to use any other form of contraception during the seven-day break provided you have taken the 21 pills properly and you start the next pack on time.

The next pack
After seven pill-free days, start your next pack. Do this whether or not you are still bleeding. You will always start a new pack on the same day of the week.

Changing to Triregol from another combined hormonal contraceptive (combined pill, vaginal ring, transdermal patch)
You should start with Triregol on the day after you took the last active tablet in your previous blister pack of contraceptive pills (or removed the transdermal patch or vaginal ring). The next pack should be started no later than on the day after the usual pill-free (or placebo, patch-free or ring-free) interval with your previous contraceptive.

Changing to Triregol from a progestogen-only pill
You can stop taking pills only containing progestogen any time, and start taking Triregol the next day at the same time point. But be sure to use additional contraceptive precautions (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

Changing to Triregol from a contraceptive injection or implant
If you have had an injection or implant of the hormone progestogen, you can start to take Triregol on the day that your next injection is due, or on the day that your implant is removed. However, you should use another method of contraception (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

Starting after childbirth or miscarriage or abortion
After a birth, abortion or miscarriage, your doctor should advise you about taking the pill.
You can start using Triregol immediately after a miscarriage or abortion which occurs during the first three months of pregnancy. In this case it is not necessary to take further contraceptive measures.
If you have had a delivery or abortion which occurs during the second three months of pregnancy, you can start taking Triregol 21-28 days after giving birth or having abortion. If you start later, an alternative contraception (such as the condom) must be used for the first 7 days of pill-taking. If you have had unprotected sex you should not start Triregol until your period starts or you are sure you are not pregnant. If you are breast-feeding, the combined pill is not recommended because it can reduce your flow of milk. If you have any questions about starting Triregol after childbirth or abortion, ask your doctor or pharmacist.

What to do if you have a stomach upset
If you have been sick or had diarrhoea within 4 hours after taking a tablet, the pill may not work. Continue to take it, but you may not be protected from the first day of vomiting or diarrhoea. Use another method, such as a condom, for any intercourse during the stomach upset and for the next seven days.

What to do if you want to delay or to shift your period
If you want to delay or to shift your period, you should contact your doctor for advice.

If you take more Triregol than you should
If you take more Triregol than you should, it is not likely that it will do you any harm, but you may feel sick, actually be sick or have some vaginal bleeding. If you have any of these symptoms, you should talk to your doctor who can tell you what, if anything, you need to do.

If you forget to take Triregol
If you forget to take a pill please follow these instructions.

If one pill is 12 hours late or less
Your contraceptive protection should not be affected if you take the late pill at once, and keep taking your next pills at the usual time. This may mean taking two pills in one day.

If you are more than 12 hours late in taking a pill, or have missed more than one pill
If you are more than 12 hours late in taking a pill, or you have missed more than one pill, your contraceptive protection may be lower so you must use extra protection. The more pills you have missed, the more risk there is that your contraceptive protection is reduced. In this case follow the instructions for daily practice:

What to do if you miss the pill at the first week
You must take the last missed tablet as soon as you remember, even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You must also use a barrier method of contraception, e.g. a condom, for the next 7 days. If intercourse has taken place during the preceding 7 days the possibility of pregnancy must be considered. The more missed tablets and the closer to the tablet-free interval this happens, the greater the risk of pregnancy.

What to do if you miss the pill at the second week
You must take the last missed tablet as soon as you remember even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. Provided that the tablets have been taken in a correct manner during the 7 days preceding the missed tablet, it is not necessary to take further contraceptive measures. However, if this is not the case, or if more than 1 tablet has been missed, you should use another contraceptive method for 7 days.

What to do if you miss the pill at the third week
You should take the last missed tablet as soon as you remember, even if it means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You should then start the next pack immediately after taking the last tablet in the current pack, i.e. without a tablet-free interval between the packs. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or break-through bleeding, on the days you are taking tablets.

You may also stop taking tablets from the current pack. In that case, you should keep a period without tablets of up to 7 days, including those days when you forgot to take your tablets, and thereafter continue with the next pack.
If you have missed tablets and then do not get a withdrawal bleed in the first normal tablet-free interval, the possibility of pregnancy must be considered.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

Common side effects (may affect up to 1 in 10 people):
depressive moods, mood swings, headaches,

feeling or being sick, , abdominal pain, cholelithiasis, acne, chloasma (yellow brown patches on the skin), breast tenderness, breast pain, bleeding from the uterus that is not due to menstruation, increase in body weight.

Uncommon side effects (may affect up to 1 in 100 people):
breast cancer, fluid retention, loss of interest in sex, increase in interest in sex, nervousness, migraine, high blood pressure, diarrohea, vomiting, rash, nettle-rash (urticaria), breast enlargement.

Rare side effects (may affect up to 1 in 1,000 people):presence of excess lipids in the blood called hyperlipidaemia, contact lens intolerance, impaired hearing (otosclerosis), blockage of a vein by a clot formed elsewhere in the body, hypersensitivity, red nodules or lumps, inflammation of the walls of the bowel (ulcerative colitis), Crohn's disease, skin disorders (erythema nodosum - a skin disease associated with joint pain, fever, hypersensitivity, or infection, and characterized by small, painful, pink to blue nodules under the skin and on the shins that tend to recur, erythema multiforme - a skin disease characterized by solid raised spots on the skin or fluid-filled blisters lesions and reddening or discoloration of the skin often in concentric zones about the lesions), breast discharge, vaginal discharge, weight loss.

Very rare side effects (may affect up to 1 in 10000 people): benignus or malignant tumor of liver, cerebrovascular accident, a movement disorder called Sydenham's chorea, visual disturbance, heart attack,, inflammation of the pancreas, a disease of the connective tissue, called systemic lupus erythematosus (SLE).

Not known (frequency cannot be estimated from the available data):
elevated blood cholesterol and triglyceride levels, irritability, cerebrovascular disorder, deterioration of epilepsy, dizziness, blockage of a blood vessel by a clot formed elsewhere in the body, , blockage of the pulmonary artery by a blood clot inflammation of a vein (usually in the legs), yellowing of the skin (jaundice),
seborrhoea (a disease appearing with scaly, flaky, itchy, and red skin), abnormal amount of hair growth on the body, sensation of heaviness, absence or suppression of normal menstrual flow, anovulatory cycle (cycle in which a woman fails to ovulate), breast disorder, abnormally infrequent menstruation.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Triregol

Store below 25 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Triregol contains

Each blister pack of tablets contains the following active substances:

6 pink tablets: each tablet contains 50 microgram levonorgestrel and 30 microgram ethinylestradiol
5 white tablets: each tablet contains 75 microgram levonorgestrel and 40 microgram ethinylestradiol
10 ochre tablets: each tablet contains 125 microgram levonorgestrel and 30 microgram ethinylestradiol

The other ingredients are:
Pink tablets:
Core: colloidal anhydrous silica; magnesium stearate; talc; maize starch; lactose monohydrate;
Coating: colloidal anhydrous silica; talc; carmellose sodium; povidone K30; Macrogol; copovidone; calcium carbonate; sucrose; red iron oxide (E172); titanium dioxide (E171).
White tablets:
Core: colloidal anhydrous silica; magnesium stearate; talc; maize starch; lactose monohydrate;
Coating: colloidal anhydrous silica; talc; carmellose sodium; povidone K30; Macrogol; copovidone; calcium carbonate; sucrose; titatium dioxide (E171).
Ochre tablets:
Core: colloidal anhydrous silica; magnesium stearate; talc; maize starch; lactose monohydrate;
Coating: colloidal anhydrous silica; talc; carmellose sodium; povidone K30; Macrogol; copovidone; calcium carbonate; sucrose; yellow iron oxide (E172); titanium dioxide (E171).

What Triregol looks like and contents of the pack
Each blister contains 21 tablets: 6 pink tablets, 5 white tablets and 10 ochre tablets.

Pink tablets: pink, bright, biconvex, circular tablets.
White tablets: white, bright, biconvex, circular tablets.
Ochre tablets:ochre, bright biconvex, circular tablets.

Packaging:
Aluminium-PVC/PVDC blister.

Pack sizes: 1 x 21 tablets, 3 x 21 tablets, 6 x 21 tablets and 13 x 21 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Gedeon Richter Plc.
Gyömrői út 19-21.
H-1103 Budapest
Hungary

Manufacturer:
Gedeon Richter Plc.
Gyömrői út 19-21.
H-1103 Budapest
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Triregol comprimés enrobés
Triregol omhulde tabletten
Triregol überzogene Tabletten
Denmark: Triregol, overtrukne tabletter
Ireland: Triregol coated tablets
United Kingdom: TriRegol coated tablets

This leaflet was last approved in May 2020.