

GLITAXON® 20 mg/ml, Solution for injection in pre-filled syringe
GLITAXON® 40 mg/ml, Solution for injection in pre-filled syringe
Glatiramer acetate

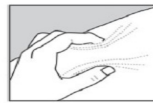


Figure-2



Figure-3

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

- Keep this leaflet; you may need to read it again.
- If you have any further questions, or any doubt, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

- 1.What is GLITAXON Solution for injection in pre-filled syringe and in which case is it used?
- 2.What you need to know before you use GLITAXON Solution for injection in pre-filled syringe?
- 3.How to use GLITAXON Solution for injection in pre-filled syringe?
- 4.Possible side effects
- 5.How to store GLITAXON Solution for injection in pre-filled syringe ?
- 6.Other information.

1.What is GLITAXON Solution for injection in pre-filled syringe and in which case is it used ?

GLITAXON is a medicine used for the treatment of remitting forms of multiple sclerosis (MS). It modifies the way in which your body's immune system works and it is classified as an immunomodulatory agent. The symptoms of MS are attributed to a dysfunction of the body's immune system. This produces patches of inflammation in the brain and spinal cord.

GLITAXON is used to reduce the number of times you suffer attacks of MS (relapses). It has not been demonstrated to be effective if you have any form of MS other than the remitting form and if you have hardly any or no relapses. GLITAXON may have no effect on the duration or the severity of an MS attack.

2.What you need to know before you use GLITAXON Solution for injection in pre-filled syringe ?

Do not use GLITAXON, Solution for injection in pre-filled syringe in the following cases :
 If you are allergic to the active substance of glatiramer acetate, or to any of the other ingredients contained in this medicine listed in section 6.

Warnings and precautions

- Talk to your doctor or pharmacist before using GLITAXON.
- If you have any kidney or heart problems, you may therefore need regular tests and checkups.
- Children : GLITAXON 20 mg/ml is not to be used in children under 12 years.

Available data regarding the use of GLITAXON 40 mg/ml for children and adolescents below 18 years are not sufficient to recommend its use.

Elderly : GLITAXON was not specifically studied in the elderly. Please ask your doctor for advice.

Other medicines and GLITAXON

Tell your doctor or pharmacist if you take, you have recently taken or may take any other medicine.
Pregnancy, Breastfeeding and fertility
 If you are pregnant or breastfeeding, if you think you are pregnant or planning to get pregnancy, ask your doctor for advice regarding GLITAXON treatment during pregnancy and/or breastfeeding.

Driving and using machines

GLITAXON is not known to influence the ability to drive or operate machines.

3. HOW TO USE GLITAXON, Solution for injection in pre-filled syringe ?

Always use this medicine by following exactly the instructions of your doctor or pharmacist.

Check with your doctor or pharmacist if in doubt.

GLITAXON 20 mg/ml
 for adults and adolescents of 12 years or more, the recommended dose is one pre-filled syringe (20 mg glatiramer acetate), administered under the skin (subcutaneously).

GLITAXON 40 mg/ml
 For adults, the dose is one pre-filled syringe (40 mg glatiramer acetate), administered under the skin (subcutaneously) three times a week injected at least 48 hours apart, for instance Monday, Wednesday and Friday. It is recommended to administer the medicine on the same days of the week, every week.

It is important to inject GLITAXON properly:

- only into the tissue under the skin (subcutaneous tissue) (see "Instructions for use", below).
- At the dose prescribed by your doctor. Use only the dose prescribed by your doctor.
- Never use the same syringe more than once. Any unused product or waste should be discarded.
- don't mix or administer at the same time the content of GLITAXON pre-filled syringe with another product.
- if the solution contains particles. Do not use it. Use a new syringe.

The first time you use GLITAXON, you will receive full instructions and you will be monitored by a doctor or a nurse. They will be with you while you inject yourself and during the half-hour following the injection, just to make sure you have no problem.

Instructions for use

Read carefully these instructions before you use GLITAXON

Before the injection, make sure you have everything you need :

- One blister with one GLITAXON pre-filled syringe.
- A container to throw the used needles and syringes.
- For each injection, take out only one blister with one pre-filled syringe from the package. Keep the remaining syringes in the box.

• If your syringe has been stored in the refrigerator, Take the blister containing the syringe at least 20 minutes before you inject the medicine, so that it warms up to room temperature.

Wash your hands thoroughly with water and soap.

Choose the injection site, using the diagram of Figure 1.

On your body, there exists seven possible areas for injection : arms, thighs, hips and belly.

On each area of injection, there are many places of injection. Choose different site for each injection. This will reduce the risk of skin irritation or soreness at the injection site. At the level of the same area, change also the site of injection. Don't use the same area each time.

Please note: Do not inject in any area that is painful or discolored, or where you feel firm knots or lumps. You should consider having a planned schedule for rotating injection sites and making a note of it in a diary. There are some sites on your body that may be difficult for self-injection (like the back of your arm). If you want to use those : you may require assistance.

Fig. 1 :

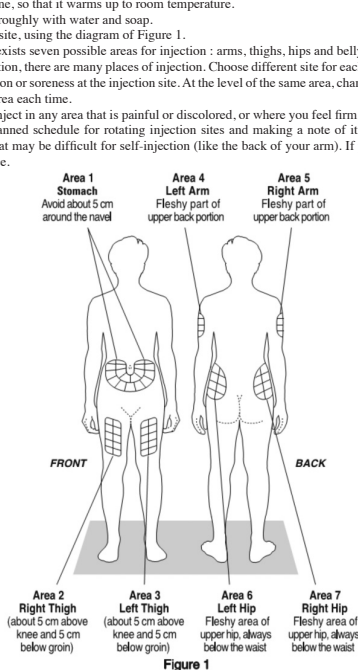


Figure 1

How to inject :

- Remove syringe from its protective blister.
- Remove the shield from the needle.
- Gently pinch up the skin with the thumb and forefinger of the free hand (Figure 2).
- Insert the needle into the skin as shown in the Figure 3.
- Inject the medicine by steadily pushing the plunger all the way down until the syringe is empty.
- Pull the syringe and needle in a straight manner.
- Discard the syringe in a container destined for safely disposing this type of waste. Do not discard used syringes with household waste but discard them thoroughly in a puncture proof container, as recommended by your doctor or nurse.

If you have the impression that the effect of GLITAXON is too strong or too weak, talk to your doctor.
 If you have used more GLITAXON than you should, consult immediately your doctor.
If you forget to use GLITAXON, use it as soon as you remember it or are able to use it. Don't use a double dose to make up for the forgotten dose.
If you stop using GLITAXON
 Don't stop using GLITAXON without consulting your doctor.
 If you have any further questions regarding the use of this medicine, ask your doctor or pharmacist for more information.

4.POSSIBLE SIDE EFFECTS ?

Like any medicine, GLITAXON, Solution for injection in pre-filled syringe can cause side effects, though not everybody gets them.

Allergic reactions (hypersensitivity)

Rarely, you may develop serious allergic reaction to this medicine.

Stop using GLITAXON and immediately contact your doctor or go to the nearest hospital emergency room, if you notice any sign of the following side effects :

- Rash (red spots or urticaria),
- Swelling of the eyelids, face or lips,
- Sudden shortness of breath,
- Convulsions (fits),
- Syncope.

Other reactions that may happen following the injection (immediate post-injection reaction)

Some people may develop one or many of the following symptoms within minutes after GLITAXON injection. These symptoms normally don't cause any problem and disappear usually within half an hour.

However, if the following symptoms last more than 30 minutes, contact your doctor or go to the nearest hospital emergency room :

- Redness of chest or face (vasodilatation),
- shortness of breath,
- Chest pain,
- pounding and rapid heartbeat (palpitations, tachycardia).

In general, the reported side effects on patients treated by GLITAXON 40 mg/ml three times a week are also reported on patients treated by GLITAXON 20 mg/ml (see the following list):

Very common (may occur in more than 1 in 10 people) :

- infections, Influenza
- anxiety, depression
- headache
- nausea
- Rash
- Joint and back pain
- feeling of weakness, cutaneous reaction at the injection site, including skin reddening, pain, swellings, itching, swelling of tissue, inflammation and hypersensitivity (these reactions at the injection site are not unusual and normally decrease with time), unspecified pain

Common (may occur in up to 1 in 10 people) :

- respiratory tract infection, stomach flu, cold sores, ear infections, runny nose, dental abscess, vaginal thrush
- non malignant skin tumors (non malignant neoplasia of the skin), tumors of tissues (neoplasia)
- swelling of the lymph nodes
- allergic reactions
- loss of appetite, weight gain
- nervousness
- altered taste, increased tightness of muscle tone, migraine, speech disorder, syncope, tremor
- double vision, eye disorder
- ear disorder
- cough, hay fever
- Anal or rectal disorder, constipation, dental caries , indigestion, trouble swallowing, bowel incontinence , vomiting
- Abnormal hepatic function tests
- ecchymosis, excessive sweating, itching, skin disorders, urticaria.
- Neck pain
- Need to quickly empty your bladder, frequent urination, inability to empty your bladder completely
- Chill, facial swelling, loss of tissue under the skin at the injection site, local reactions, peripheral edema due to fluid accumulation, fever.

Uncommon (may occur in maximum up to 1 in 10 people) :

- abscess, infection of the skin and soft tissues, boils, shingles, infection of the outer ear and kidneys
- skin cancer
- Increase of the number of white blood cells, decrease of the number of white blood cells, enlargement of the spleen, decrease of the number of platelets, change of the shape of white blood cells.
- Enlarged thyroid, overactive thyroid
- low alcohol tolerance, gout, increase in blood fat levels, increased sodium in the blood, decrease in serum ferritin
- Strange dreams, confusion, euphoria, seeing, hearing, smelling, tasting or feeling things that don't exist (hallucinations), aggression, abnormal elevated mood, personality disorder, suicide attempt.
- hand numbness and pain (carpal tunnel syndrome), mental disorders, seizure (Convulsion), problems with handwriting and reading, muscle disorders, problems with movements, muscle spasm, nerve inflammation, abnormal nerve-muscle link leading to abnormal muscle function , involuntary rapid movement of the eyeballs, paralytic, foot drop (peroneal paralysis), unconscious state (stupor), visual blind spots
- cataract, eye lesion in the cornea, dry eye, eye bleeding, drooping eyelid, pupil widening, withering of the optic nerve leading to vision disorders
- additional heartbeat, slow heartbeat, episodic rapid heartbeat
- varicose veins
- periodic breathing cessation, nosebleeds, abnormally fast or deep breathing (hyperventilation), feeling of tight throat, lung disorders, inability to breathe due to throat tightness (feeling of suffocation).
- intestinal inflammation, polyps in the colon, burping , esophageal ulcers, gum inflammation, rectal bleeding, swelling of the salivary glands
- kidney stones, liver enlargement
- swelling of the skin and soft tissues, skin contact rash, red and painful skin nodules, cutaneous nodules
- joint swelling, inflammation and pain (arthritis or osteoarthritis), bursa inflammation and pain, a sac filled with liquid, bordering the joint (existing in some joints), flank pain, decreased muscle mass
- blood in urine, urinary stones, other disorders in the urinary system, abnormal urine
- abortion
- breast swelling, difficulty in erection, descent or slipping out of place of pelvic organs (pelvic prolapse), prolonged erections, prostate problems, anomaly of Pap smear (abnormalities of cervical smear), testicular problems, vaginal bleeding, vaginal disorder.
- cysts, hangover, lower than normal body temperature (hypothermia), non-specific inflammation, tissue destruction at the injection site, mucous membrane problems.
- disorders after vaccination

Reporting of side effects

If you feel any side effect, talk to your doctor or pharmacist. This includes also any side effect that is not mentioned in this leaflet. You can also report the side effects directly via the reporting national system : National Centre of pharmacovigilance (CNPV). By reporting side effects, you can provide more information on the safety of this medicine.

5.HOW TO STORE GLITAXON, Solution for injection in pre-filled syringe ?

Keep out of the sight and reach of children.

Store in a refrigerator (between 2°C - 8°C).

Do not freeze.

Keep the pre-filled syringe in the outer packaging, in order to protect from light.

Do not use this medicine after the expiry date mentioned on the packaging, after «EXP». The expiry date refers to the last day of this month.

Discard any syringes that contain particles.

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

6.OTHER INFORMATION

What does GLITAXON, Solution for injection in pre-filled syringe contain?

	GLITAXON 20 mg/ml	GLITAXON 40 mg/ml
active substance	20 mg/ml of Glatiramer Acetate	40 mg/ml of Glatiramer Acetate
Excipients	Mannitol, W.F.I.....S,Q	

What GLITAXON, Solution for injection in pre-filled syringe, looks like and content of the outer packaging :

GLITAXON is presented as a solution for injection in a pre-filled syringe and is a sterile, clear solution, free visible particles. If the solution contains particles, discard it and start again. Use a new syringe.

GLITAXON is available in a pack of 02 pre-filled syringes of 1 ml containing 20 mg or 40 mg.

Marketing Authorisation Number:

GLITAXON 20 mg/ml : 9233731H

GLITAXON 40 mg/ml : 9233732H

Conditions of prescription: List I

Marketing Authorisation Holder & Manufacturer :

Les Laboratoires Médis.

Tunis Road - KM 7 - BP 206 8000 Nabeul - Tunisia

Tel : +216 72 235 006 / Fax : +216 72 235 016

E-mail : contact@labomedis.com

This leaflet was last revised in May 2019 version N°: « 00 »

This is a Medicine

- A medicine is a product but not like any others product.
- A medicine is a product that affects your health.If it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of you Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and your pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, don't increase the doses without docto's advice.

Keep all medicine out of reach of children

