

Mylan glatiramer acetate (MY lan, gla TIR a mer, ASS e tate)

Generic name: glatiramer acetate (gla TIR a mer, ASS e tate)

What is Mylan glatiramer acetate?

Mylan glatiramer acetate is a random assortment of four amino acids (L-glutamate, L-alanine, L-tyrosine, and L-lysine). These amino acids are found in myelin basic protein, the most common protein in myelin.

Mylan glatiramer acetate shifts the immune reaction away from T_H1 type cells (which tend to promote autoimmune reactions) and towards T_H2 type cells (which tend to block autoimmune disease). This medicine does not suppress the immune system, and patients taking it do not have an increased risk of infection.

Mylan glatiramer acetate slows the course of multiple sclerosis when used regularly over long periods of time. It does not improve existing symptoms and is not used to treat acute MS attacks.

Starting on Mylan glatiramer acetate.

To obtain Mylan glatiramer acetate

1. A start form must be completed and faxed to the Mylan Advocate program. This program, operated by Novartis, the manufacturer of Mylan glatiramer acetate, will start the process of obtaining the medication. Pharmacotherapy clinic staff can assist with completion of these forms and getting insurance approval. It takes 1-2 weeks to get insurance approval. Sometimes, insurance denials and appeals may take longer.
2. Insurance often pays only part of the cost of Mylan glatiramer acetate. The contract between the patient and the insurance company specifies the amount of deductibles and copayments.
 - a. The deductible is the amount patients must pay each year before their insurance starts covering costs.
 - b. The copayment is the amount patients must pay for each medical bill.
For medications, the copayment is often a percent of the medication's cost. Pharmacotherapy clinic staff can assist in getting the manufacturer or foundations to decrease the cost of deductibles and copayments.
3. The medication is not stocked in your pharmacy. It must be shipped overnight from a distributor to either your home or your pharmacy (depending on insurance requirements). Pharmacotherapy clinic staff can assist in the shipping process.

After the medication arrives, those living near the Center should contact the pharmacotherapy clinic or MS Center nurses for training on how to administer the Mylan glatiramer acetate. Those living outside our region will have training done by visiting nurses provided by Novartis, the manufacturer.



Multiple Sclerosis Center

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Seattle, WA 98122
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www.swedish.org/ms or
www.swedishmscenter.org

Mylan glatiramer acetate can be started at full dose without a taper.

Safety Monitoring

- Safety tests are not required on Mylan glatiramer acetate

How should Mylan glatiramer acetate be taken?

Mylan glatiramer acetate is given by injection under the skin.

Volume injected: 1mL (1 cc).

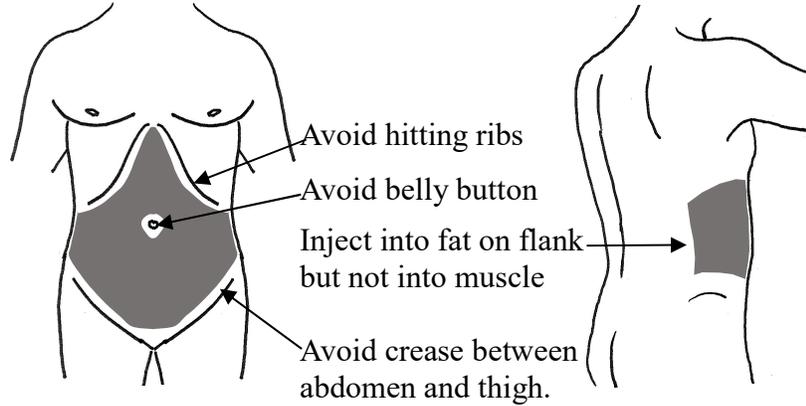
Needle size: 29 gauge, ½ inch length

Autoinjector: available for those who want to use it.

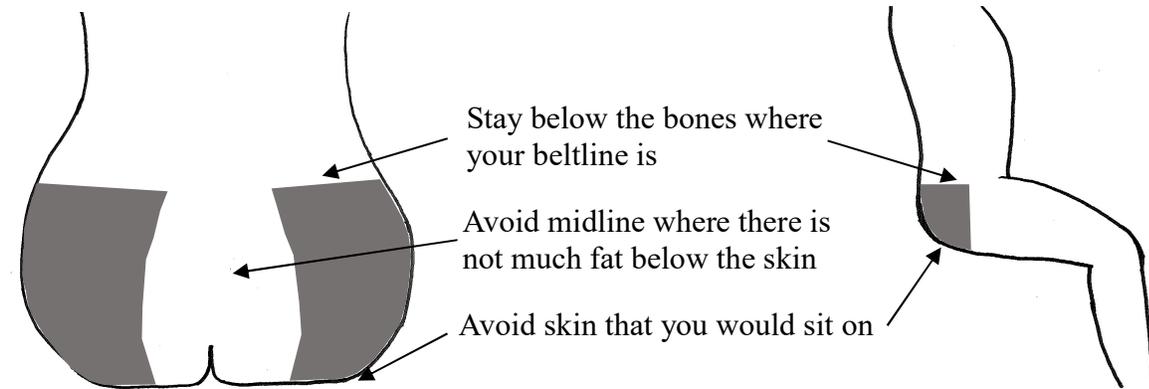
Injection site locations: Injections should be rotated among various sites. Sites include front of the thighs, back of arms, buttocks and abdomen.

Injection sites: The medication guide provided by the manufacturer contains a diagram of where injections can be given. However, injections can be given in a wider territory than described in the medication guide. Below are the areas that we recommend using.

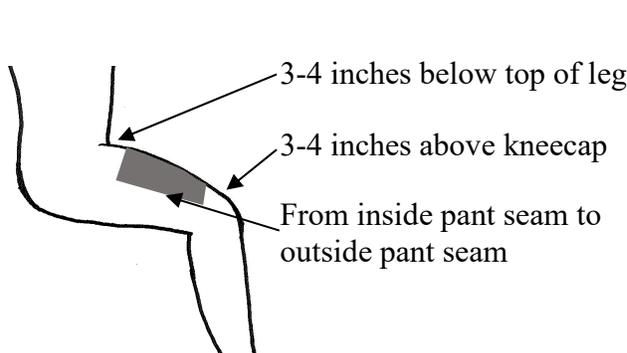
Abdomen:



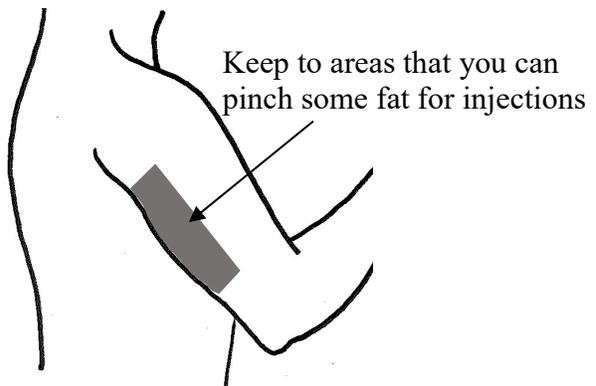
Buttock:



Thigh:



Arm:



Laboratory tests: are not needed with this medication.

What if a dose is missed?

Take the next dose as soon as you remember. Do not take more than one dose in an 18 hour period.

How should Mylan glatiramer acetate be stored? This medication should be refrigerated. If refrigeration is not available it may be kept at room temperature for up to 30 days.

How supplied: Mylan glatiramer acetate comes in prepackaged kits containing all needed supplies. It comes in prefilled syringes. There are two forms of Mylan glatiramer acetate.

- 20mg syringes given once a day. Each carton contains 30 doses (1 month)
- 40mg syringes given every other day. Each carton contains 12 doses (1 month)

What are the common side effects?

- Injection site reactions: It is common to get a red spot at the site of the injection. This is sometimes accompanied by a lump under the skin or itching. Injection site reactions can be minimized by:
 - Keeping the needle and other equipment clean.
 - Rotating the sites. If particular body locations are more prone to these reactions, those sites may be removed from the rotation.
 - Some find that applying warm packs before or after the injection may help. Others find that cool packs help. Experiment to see which works best for you.
 - Set the needle depth deeper to keep the medication from reacting just beneath the skin.
 - Don't remove the air bubble, and don't squirt the drug out the end of the needle that you use to inject with. The medication left on the tip of the needle may track to the surface of the skin.
 - Lidocaine creams such as Emla[®] or Elamax[®] may decrease injection site pain on the surface of the skin
 - Hydrocortisone cream may decrease the inflammation.
- Injection site bruising: This is caused by blood leaking along the needles tract. This can be minimized by applying firm pressure to the injection site for a full minute, immediately after removing the needle.

- Immediate post-injection reaction: This may occur if the medication is injected into a vein. The medication enters the bloodstream very quickly when this happens. This reaction occurs immediately after an injection, within a few minutes. About 16% of people on the medication experience this, most only once. Though frightening, the systemic reaction is not dangerous. It can include chest pain, flushing, shortness of breath, palpitations, anxiety and throat constriction. These symptoms are self-limited, usually lasting no more than 15-20 minutes. Those that experience this side effect should lie down until the symptoms resolve. It is not necessary to call 911. If symptoms occur outside of the immediate injection time period, it is not likely to be a systemic reaction and 911 should then be called. Cooling the injection site with ice before the injection constricts the blood vessels in the skin, which decreases the risk of this reaction.
- Lipoatrophy. Any injection under the skin can damage the fat under the skin, causing an area of fat loss and a permanent dent of the skin. This is called lipoatrophy. It can be minimized by rotating injection sites.

Sharps container: Needles must be disposed of properly. We recommend using a needle clipper such as the Becton Dickinson Safe-Clip™ (www.bd.com/us/diabetes). This clips off the needles, allowing the rest of the syringe to be disposed of in the trash. Other disposal options may be available through your local solid waste disposal company.

Company Support:

Mylan Advocate 1-855-452-8672 Provides financial assistance, insurance assistance, information about Mylan glatiramer acetate and multiple sclerosis.

www.glatirameracetate.com

Insurance billing code: J1595



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