

CinnoVex®

INTERFERON BETA - 1a

30 mcg/0.5ml
Sterile Pre-filled Syringe

Pharmacological -Therapeutic Category:

Interferon – Immunomodulator

Pharmacodynamics - Pharmacokinetic:

Mechanism of action

Recombinant interferon; antiviral, antiproliferative, immunoregulatory protein; alters response to surface antigen and may enhance immune cell activities.

Pharmacokinetic:

Onset of action: 12 hr.

Duration: 4 days

Peak plasma time: 7.8-9.8 hr.

Half-Life: 8.6-10 hr.

Indications

CinnoVex® is used for treatment of relapsing form of multiple sclerosis (MS). It has been shown to reduce the number and the severity of relapses and to slow the progression of disability.

Dosage and administration

Recommended Dose

Adult: The recommended dosage for the treatment of relapsing MS is 30 micrograms (0.5 ml solution) once a week.

Pediatric: The safety and efficacy of CinnoVex® in Children below 12 have not yet been established.

Method of administration

The only recommended rout of administration of CinnoVex®

injection is intramuscular (IM) route and should not be administered by Intravenous or Sub-cutaneous routes. The best sites for IM injection are the thigh and upper arm.

Contraindications

- Initiation of treatment in pregnancy.
- Patients with a history of hypersensitivity to natural or recombinant interferon beta or to any excipients of CinnoVex®.
- Patients with current severe depression and/or suicidal ideation.

How to inject CinnoVex®

You should have had training in how to inject CinnoVex®. These notes are a reminder. If there's anything you're not sure about, check with your doctor or pharmacist.

Where to inject

CinnoVex® is injected into a muscle, for example, the upper thigh muscle. Injection of CinnoVex® into the buttocks is not recommended.

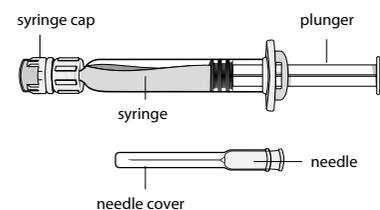
Getting Ready prior to injection

Remove one sealed plastic tray from the refrigerator

- Check the expiry date on the lid of the tray. Do not use it if it is out-of-date.

- Leave it at room temperature for half an hour. This makes the injection more comfortable than injecting straight from

Content of the plastic tray



a refrigerator.

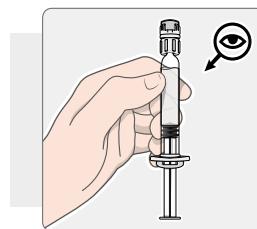
- Do not use external heat sources such as hot water to warm the syringe.

- Wash your hands thoroughly with soap and water and dry them.

How to prepare to inject

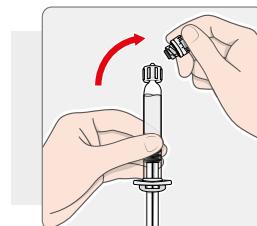
1- Check the liquid in the syringe

It should be clear and colourless. If the solution is cloudy, coloured or contains any floating particles, do not use the pre-filled syringe.



2- Remove the syringe cap

Make sure the cap is intact and has not been opened. If it looks like it has been opened, do not use that syringe. Hold the syringe so that the cap is facing up.



Bend the cap at a right angle until it snaps off.

Do not touch the connection port.

Do not push on the plunger.

3- Fit the needle

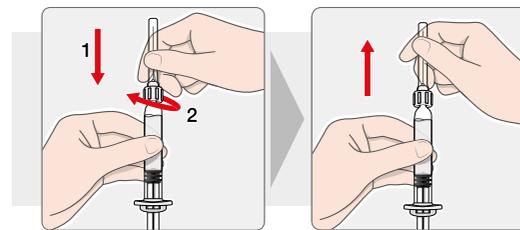
Open needle to expose the connection port. Keep the cover on.

Press the needle onto the syringe.

Turn it clockwise until it locks into place.

Make sure the injection needle is firmly attached to the syringe. Otherwise it may leak.

Now pull off the plastic needle cover. Do not twist it.

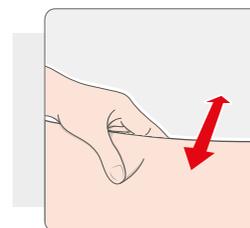


How to inject

Clean and stretch the injection site

If you need to, use an alcohol wipe to clean the skin at the injection site you've chosen. Allow the skin to dry.

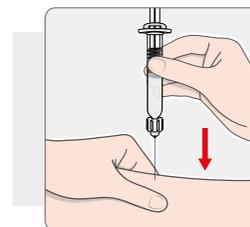
With one hand, stretch the skin around the injection site. Relax your muscle.



Insert the injection needle with a quick dart-like thrust at right angles to the skin, into the muscle.

The needle must go all the way in. Press the plunger slowly until the syringe is empty.

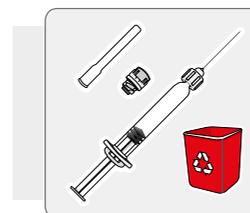
Pull the needle out. Keep the skin stretched tightly or squeeze the skin around the injection site, and pull out the needle.



How to Dispose of the rubbish properly

After you have finished each injection, put the needle and syringe into a special container (such as a sharps bin), not in ordinary rubbish.

Waste paper and used wipes can be put in an ordinary rubbish bin.



Adverse drug Reactions

Injection site reactions, Headache, Flu-like syndrome, Muscle ache, Nausea, URT infection, Pain, Fever, Chills, Cough, Nausea, Diarrhea, Dizziness, Infection, Dyspepsia, Asthenia, Abdominal pain, Joint pain, Chest pain, Depression, Suicide, and Psychotic Disorders, Hepatic Injury, Anaphylaxis and other allergic-reactions, Congestive Heart Failure, Low blood pressure, Decreased Peripheral Blood Counts, Seizures, Autoimmune disorders, Thyroid problems, Unusual tiredness or weakness, Weight changes (gain or loss)

Pregnancy Risk Factor:

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Lactation

There are no data on the excretion of CinnoVex® into human milk. Caution be used when administering CinnoVex® to nursing women.

Drug Interactions

There are no known significant interactions for CinnoVex®.

Storage

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the label. Store in the original package. Store in a refrigerator (between 2°C and 8°C). Do not freeze. CinnoVex® can also be stored at room temperature (25°C) for up to one week.

Packaging

CinnoVex® is available in packs containing 4 sterile pre-filled syringes, 4 needles and a PIL.

