

Instructions for Use

Enbrel[®]

(etanercept)

Dose-dispenser cartridge for use in a Multi-Use, Single-Patient device

For Subcutaneous Injection Only

Important Information

- Keep this Instructions for Use, it shows step-by-step how to prepare and give an injection.
- Only use Enbrel after you read and understand this Instructions for Use.
- Only use Enbrel after you have received training from your healthcare professional.
- Your Dose Dispenser Cartridge contains a single dose of Enbrel and must only be used with your Multi-Use, Single-Patient (MUSP) Device.
- Dose Dispenser Cartridge and MUSP Device will be referred to as “Cartridge” and “Device” in this Instructions for Use.
- If this is the first time you are using your Device, make sure you follow the setup instructions in the separate User Manual. You will not be able to use your Device until you complete the setup.
- **Do not** attempt to use your Cartridges with any other Device.
- **Do not** share your Cartridges or your Device with another person.
- **Do not** shake your Cartridges or your Device containing a Cartridge.
- **Do not** reuse your Cartridge if the needle cap has been removed.
- Avoid spilling liquid on your Cartridges or your Device. Never rinse or put your Cartridges or your Device under water.
- Refer to the additional Device User Manual for accessing menus, using a Training Cartridge, advanced use and troubleshooting error messages.

Storage

- Store Cartridges in the refrigerator between 2 °C to 8 °C. **Do not** freeze your Cartridges. **Do not** store your Cartridges in your Device.
- Store Cartridges in their original Carton until use to protect from direct sunlight.
- You may store your Cartridges at room temperature up to 25 °C for up to 4 weeks. **Do not** return them to the refrigerator after they have reached room temperature.
- Keep your Cartridges and your Device out of sight and reach of children and adolescents.
- Refer to your Device User Manual for how to store and clean your Device.

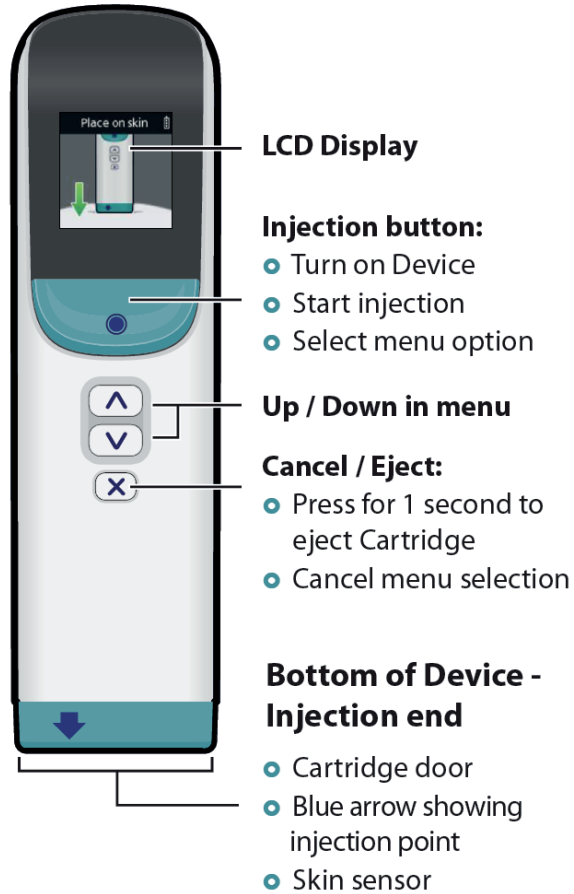
Supplies you need

- **Gather** the following supplies on a clean flat surface:
 - Enbrel Carton containing Cartridges
 - your MUSP Device
 - alcohol wipes
 - clean cotton balls or gauze pads (not included)
 - a suitable sharps container (not included).
- **Do not** use if the Carton is dropped or damaged.
Note: If you do not have everything you need, ask your healthcare professional.

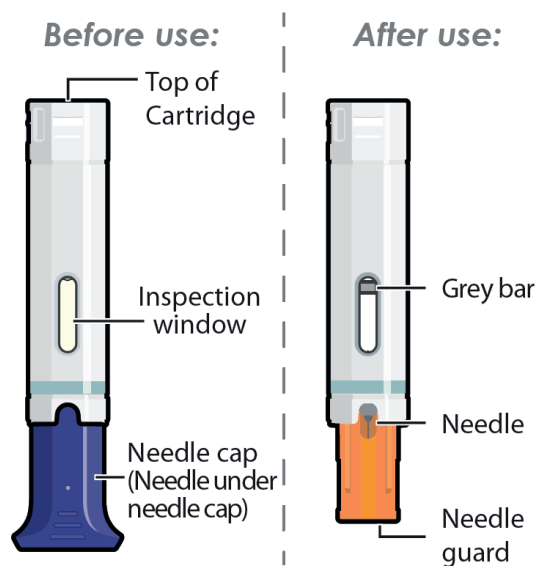
Your Device:

Refer to User Manual for more information.

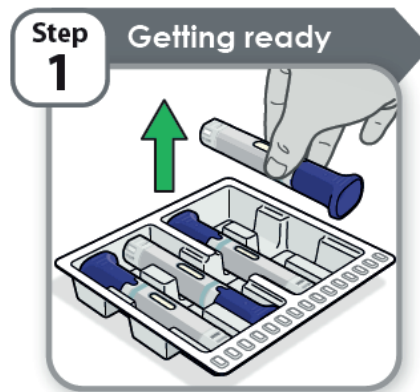
Top of Device



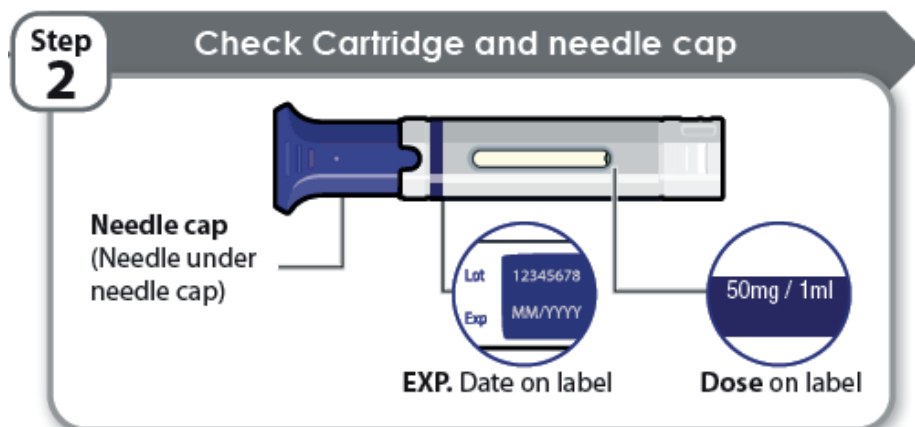
Your Cartridge:



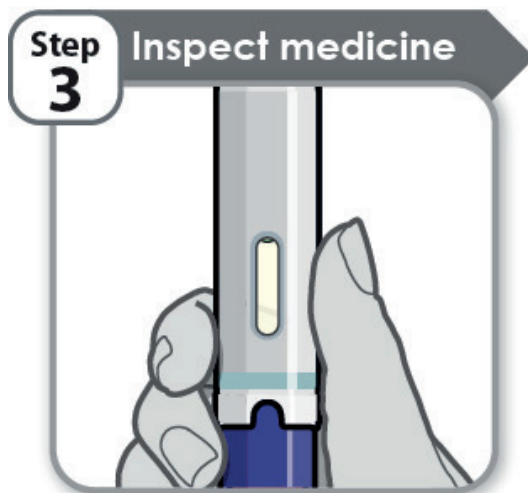
Preparation Steps



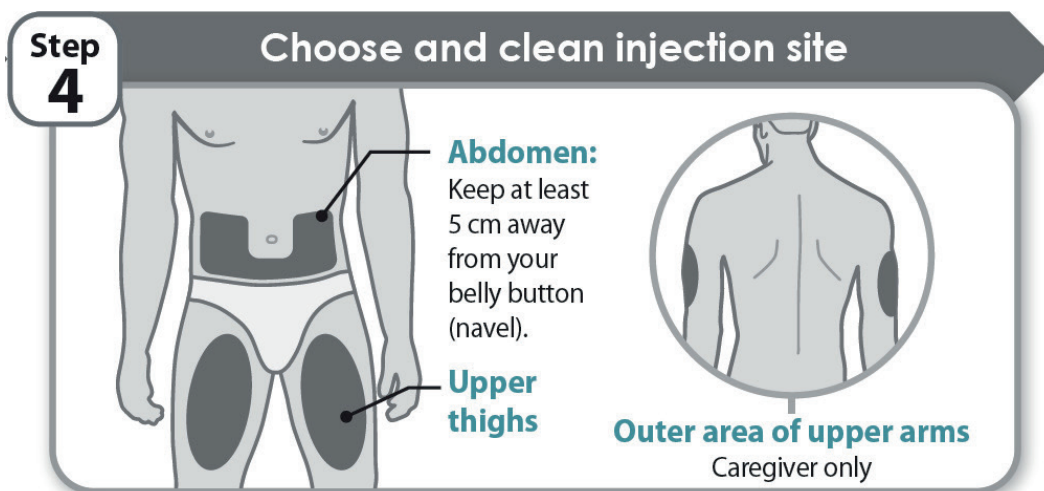
- **Remove** 1 Cartridge from the tray inside the Carton.
- **Put** the Carton and tray with any unused Cartridges back in the refrigerator.
- **Wash** and dry your hands.
- For a more comfortable injection leave your Cartridge at room temperature for approximately **15 - 30 minutes** away from direct sunlight.
Do not use any other methods to warm up your Cartridge.



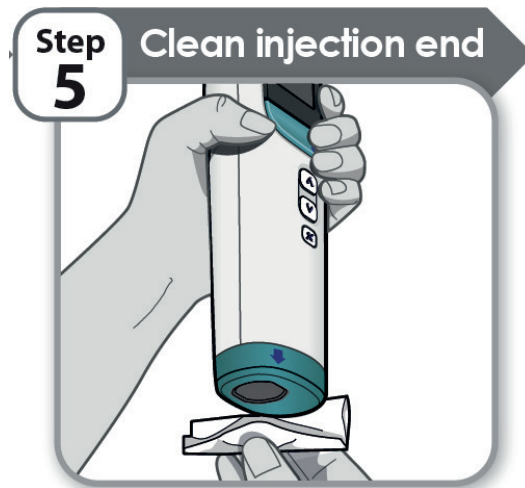
- **Check** the expiration date and medication dose printed on the label. **Do not** use if the expiration date has passed or if it is not your prescribed medication dose.
- **Check** your Cartridge, **do not** use if:
 - it has been dropped even if it does not look damaged
 - it is damaged
 - the needle cap is loose
 - it has been frozen or exposed to heat
 - it has been at room temperature for more than 4 weeks
 - it has been returned to the refrigerator after reaching room temperature.
- **Do not** remove the needle cap until instructed to do so.



- **Inspect** the medicine through the Inspection window, it should be clear or slightly opalescent, colourless to pale yellow or pale brown, and may contain small white or almost transparent particles of protein, this is normal.
- **Do not** use the medicine if it is discoloured, cloudy, or has particles other than those described above.
- **Do not** shake your Cartridge.
Note: If you have any questions about your medicine, contact your healthcare professional.

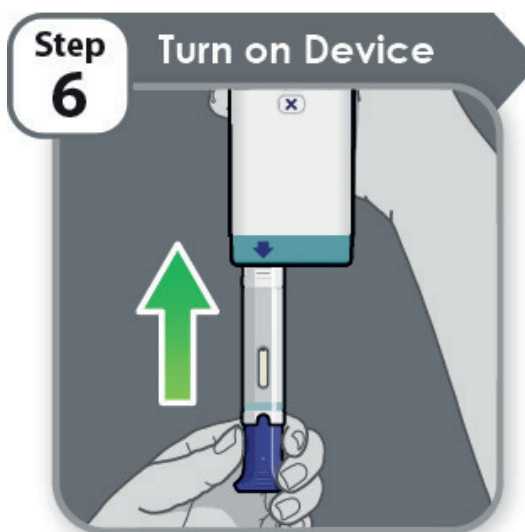


- **Always choose** an area in your abdomen, upper thighs or the outer area of the upper arms (caregiver only).
- **Choose** an injection site at least 3 cm from where you last injected and at least 5 cm away from your belly button (navel).
- **Do not** inject into bony areas or areas on your skin that are broken, bruised, red, sore (tender) or hard. Avoid injecting into areas with scars or stretch marks.
- **Do not** inject through your clothes.
Note: If you have psoriasis, **do not** inject directly into any raised, thick, red, or scaly skin patches or lesions on your skin.
- **Clean** your injection site with the supplied alcohol wipe and **allow to dry**.

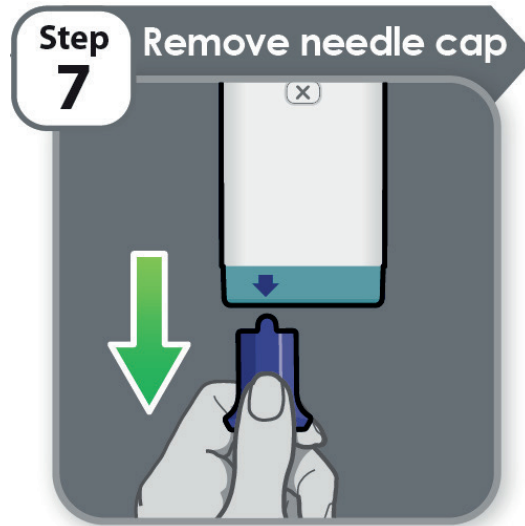


- **Clean** the injection end of your Device with the separate supplied alcohol wipe.
- **Allow** the injection end to dry before giving an injection.

Injection Steps



- **Push** your Cartridge firmly through the Cartridge door until you cannot push it any further. Your Device will turn on when your Cartridge has been inserted correctly.
- **Check** the Display shows your correct dose and the expiration date has not passed.
Note: Your Device will turn off after 90 seconds of inactivity. Press and hold the Injection button to turn your Device back on.



- **Remove** the needle cap by pulling it firmly downwards.
- **Dispose** of the needle cap in a suitable sharps container.
- **Inject** as soon as possible after removing the needle cap.
- **Do not** replace the needle cap.

Caution: Do not insert your fingers into your Device after removing the needle cap to avoid a needle stick injury.

Note: To cancel the injection and eject your Cartridge, press the Cancel / Eject button  for 1 second.

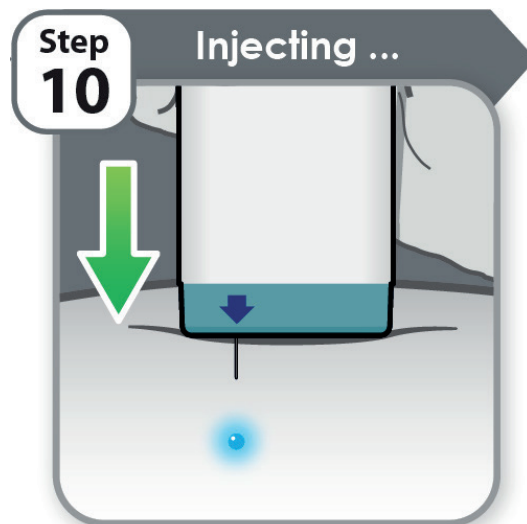


- **Place** your Device with the **blue arrow** pointing at 90 degrees towards your injection site.
- **Make sure** you can see the Display on your Device.
- **Do not** pinch the skin around your injection site.

Caution: If you drop your Device with a Cartridge inserted, eject and dispose of your Cartridge. Contact your healthcare professional for advice.



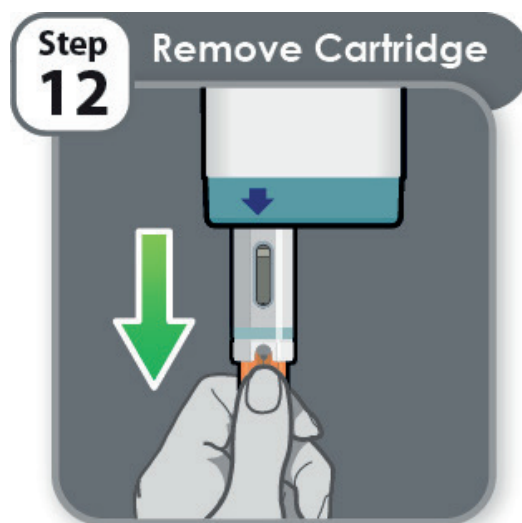
- **Press & hold** the Injection button to begin your injection when instructed by the Display.
Note: You can release the Injection button after your injection has started.



- **Hold** your Device against your skin and wait while your medication is injected.
- **Watch** the Display on your Device.
- **Do not** move, tilt or remove your Device from your skin until instructed by the Display.
Note: If you remove your Device before instructed, **do not** place it back on the injection site or inject another dose. Contact your healthcare professional for advice.



- **Lift & hold** your Device away from your skin. Your Device will display that your injection is complete.
- **Wait.** Your Cartridge will be partially ejected from the bottom of your Device. This may take up to 10 seconds.
Do not cover the bottom of your Device during this time.
Do not insert your fingers inside your Device as the needle will be exposed during this time.
- If you notice a spot of blood at the injection site, press a cotton ball or gauze over the injection site for 10 seconds. **Do not** rub.



- **Pull** your Cartridge straight out after your Device has partially ejected it.
- **Check** your Cartridge is empty of medicine with a grey bar visible in the Inspection window. If not, you may not have received your full dose. Contact your healthcare professional for advice.
- **Do not** reuse your Cartridge or reinsert it into your Device.
- **Dispose** of the used Cartridge straight away in a suitable sharps container as instructed by your healthcare professional or pharmacist and in accordance with local health and safety laws.

Instructions for use - date of last amendment: July 2021