

INSTRUCTIONS FOR USE

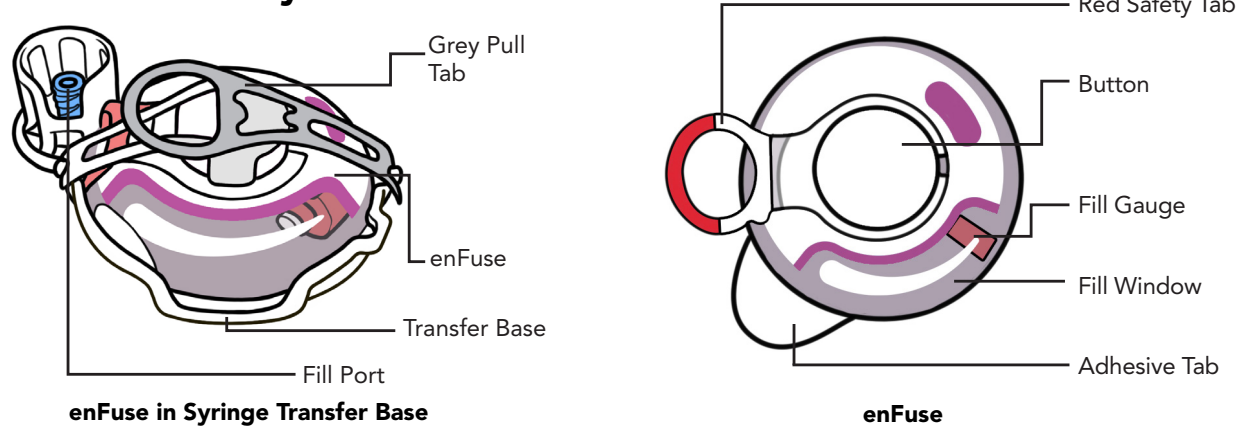
enFuse 20 mL ST System

For abdominal subcutaneous delivery of medicinal products

Single-Use On-Body Delivery Device

EN

Parts of enFuse System



Read these Instructions for Use before you start using the device and each time you get a new device as there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Your healthcare provider should demonstrate how to use the device before you use it for the first time. Ask your healthcare provider about any instructions you do not understand. If you have questions, concerns, or need of help, please call Enable Injections at 1-513-326-2800.

The Intended Purpose – For abdominal subcutaneous delivery of medicinal products
Indications for Use – The on-body delivery device system is intended for subcutaneous abdominal bolus administration of drug or biologic products with a viscosity between 8.5cp-16cP in accordance with the drug product requirements.
Patient Target Group(s) - Adults (age 18+)
Intended Users – Health Care Providers & Adults (age 18+)

Product Description:

The enFuse System is a sterile, non-pyrogenic, user-filled, single-use, fixed-dose subcutaneous dose delivery system. The finished device consists of the enFuse (on-body delivery device) and syringe transfer device (Transfer Base). The enFuse utilizes an elastomeric balloon to deliver medicinal product, and contains an integrated needle that is inserted into the subcutaneous space once the Button is depressed. The enFuse design is “constant pressure” rather than a pre-set constant flow rate; target in vitro flow rates are achieved by customized needle sizes. An adhesive backing on the enFuse, exposed upon removal of the enFuse from the Transfer Base, allows for direct attachment to the skin during subcutaneous administration. The Transfer Base is intended for one (1) single-use syringe insertion and transfer of medicinal product upon attachment of a pre-filled, pre-measured syringe with a luer fitting (compatible with ISO 80369-7 compliant syringes). The Enable enFuse is fully mechanical and does not contain any electronics or software.

Clinical Benefit:

A large volume, hands-free dose administration of a medicinal product to the abdominal subcutaneous space which improves patient management by reducing the burden on the user.

Selecting Correct enFuse Configuration:

Note: This information is provided to assist the prescribing health care provider. The needle inner diameter can be found on the product labeling.

The flow rate from the enFuse is determined by a number of variables both internal to the device design (i.e. needle inner diameter) and external (patient backpressure, medicinal product viscosity). The anticipated flow rates from each 20mL enFuse configuration (containing a needle with an inner diameter of 0.165mm and 0.198mm, respectively) for a given range of medicinal product viscosities are provided in Flow Rate Table.

Determination of the appropriate enFuse configuration can be made by comparing the high and low flow rate ranges anticipated for the nominal viscosity of the medicinal product with the medicinal product labeling requirements. If the potential medicinal product viscosity is known to vary outside of 30% from the listed value, the full potential flow rate range can be determined by the highest flow rate of the low end of the viscosity and the lowest flow rate of the high end of the viscosity. For example, if a medicinal product viscosity may vary between 8 and 12 cP (such as from manufacturing/concentration variation), the resulting flow rate range from the enFuse may vary from 9 - 53 mL/hr for the 0.165mm needle. This flow rate range can then be compared to the medicinal product labeling to ensure safe and effective delivery with the enFuse System.

Viscosity (cP)	Flow Rate Table			
	Needle ID - 0.165mm		Needle ID - 0.198mm	
	Flow Rate Range (mL/hr)	20mL Dose Time Range (minutes)*	Flow Rate Range (mL/hr)	20mL Dose Time Range (minutes)*
8	53 - 14	22 - 85	108 - 29	11 - 41
10	43 - 11	28 - 106	87 - 23	13 - 51
12	36 - 9	33 - 128	73 - 20	16 - 60
14	31 - 8	39 - 147	63 - 17	19 - 71
16	27 - 7	45 - 172	55 - 14	22 - 82

* Time Range is an estimation that will vary based on the patient's unique subcutaneous anatomy.

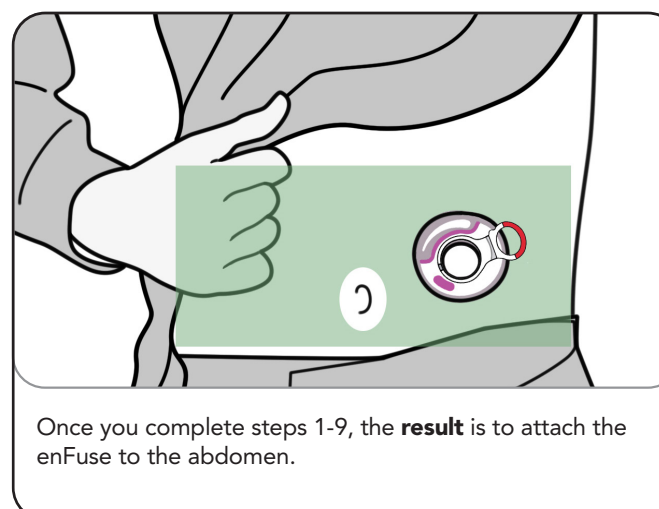
If it is unclear whether a medicinal product is compatible with the enFuse System, contact Enable Injections: email medinfo@enableinjections.com or call 1-513-326-2800.

Warnings:

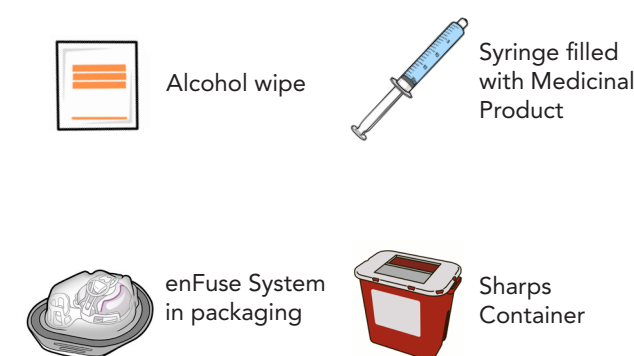
- Warning!** Keep away from children 3 years and younger. Contains small parts.
- Do not** use enFuse if tamper-proof label has been broken
- Do not** use if you dropped enFuse System or if it appears damaged
- Do not** use if sealed plastic tray is open or damaged
- Do not** use if expiration date on the box has passed
- Do not** reuse enFuse
- Do not** store filled device
- Do not** touch the white adhesive on bottom of enFuse before attaching to abdomen
- Do not** let clothes touch the clean site
- Do not** remove enFuse from skin until Button pops out
- Do not** throw away (dispose of) enFuse into trash
- Do not** remove enFuse from skin during dose delivery
- Do not** use materials to hold device in place that could compress enFuse against skin
- Do not** put any objects in the fill port other than the filled syringe

Precautions:

- Do not** use enFuse if patient has a skin condition on their abdomen (delivery site)
- Ensure the patient is wearing loose clothes so that they do not get in the way of the enFuse
- Do not** store enFuse outside of storage conditions
- Do not** use enFuse outside of use conditions
- Do not** apply enFuse along the belt line or on areas where the enFuse will be affected by folds in the skin
- Do not** remove Red Safety Tab until enFuse is attached to body
- Choose dose delivery site at least 2.5 cm from the edge of patient's belly button and the edge of enFuse, and 2.5 cm from last dose delivery site. Use the enFuse on abdomen only.
- Do not** bathe, shower, exercise, use hot tubs, whirlpools, or saunas. Avoid getting abdomen wet. enFuse is not waterproof. Water or sweat may loosen enFuse from skin
- Do not** sleep during dose delivery
- Avoid engaging in intense physical activity
- Do not** bump or knock enFuse
- Do not** bump the enFuse Button



Supplies required for Dose Delivery



Fill enFuse with Medicinal Product

1

- Wash your hands well with soap and water.
- Dry your hands.
- Peel back the cover and remove the clear packaging insert.

Remove enFuse and the surrounding Transfer Base from the packaging. Place it on a clean, flat surface.

2

- Pick up the syringe filled with Medicinal Product
- The filled syringe may have a luer cap; if so, twist to the left (counter-clockwise) to remove the cap.
- Twist** the filled syringe tip to the right (clockwise) into the Fill Port until it is tight.

⚠ Device residual volume up to 0.5mL

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- Firmly push the syringe plunger down.
- The syringe plunger may be hard to push.
- Watch the Fill Gauge advance as Medicinal Product is pushed into enFuse.

Identify and Clean the Delivery Site

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- Make sure the syringe is empty. If needed, press firmly down on the syringe plunger again.
- Do not** remove empty syringe from Transfer Base.
- After the enFuse is filled, continue with the preparation and dose delivery.
- Do not** store filled enFuse.

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Dose Delivery Area

- Determine where to place the enFuse on the bare abdomen.
- Use** the enFuse on abdomen only.
- Choose a site:
 - At least 2.5 cm from the edge of patient's belly button and the edge of the enFuse.
 - AND
 - At least 2.5 cm from the last site.
- Avoid** site that is tender, bruised, red, hard, irritated, scarred, tattooed, or has stretch marks.
- Do not** apply the enFuse along the belt line or on areas where the enFuse will be affected by folds in the skin.
- Ensure** the patient is wearing loose clothes so that they do not get in the way of the enFuse.

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- Clean site with an alcohol wipe.
- Allow the site to dry for at least 30 seconds.
- Do not** touch, fan, blow, or let clothes touch the clean site.

Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
	Country of Manufacture & Date of Manufacture	Indicates the country where the medical device was manufactured and the date of manufacture
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Use by date	Indicates the date after which the medical device is not to be used
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed
	Keep dry	Indicates a medical device that needs to be protected from moisture
	Unique device identifier	Indicates the manufacturer's device identifier so that a specific medical device can be identified
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	Hazardous substance symbol for Cobalt material	Indicates that material is a hazardous substance on labelling
	Medical Device	Indicates that the item is a Medical Device
	Authorized representative in European Community	Indicates the authorized representative in the European Community
	CE Marking	Signifies European technical conformity
	Single Sterile Barrier System	Indicates a single sterile barrier system
	Quantity	Quantity of devices contained inside the commercial packaging
	Emergo Europe Westervoortsedijk 60, 6827 AT Arnhem The Netherlands	Manufactured by: Enable Injections, Inc. 2863 E. Sharon Road Cincinnati, OH 45241, USA
	EnableInjections.com/patent	10131899 Rev. 02 Issued 09DEC2024
	EnableInjections.com/ifu	Manufactured in USA

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Remove enFuse from Transfer Base and Attach to Abdomen

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- Grasp the Grey Pull Tab and pull. Allow both the Grey and Clear Pull Tabs to fall to the side.
- The tabs may fall to the side or come off completely.

⚠ **Do not** remove the Red Safety Tab until the enFuse is attached to body.

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- Hold the sides of enFuse and pull it straight up to remove it from the Transfer Base.
- ⚠ **Do not** touch the adhesive on the bottom of the enFuse or fold the adhesive onto itself.
- The White Adhesive will stay attached to the enFuse and the Clear Liner will stay attached to the Transfer Base.
- ⚠ Ensure site has been cleaned before attaching enFuse.

White Adhesive
Clear Liner

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Fill Window

- Position the enFuse so the Fill Window is pointed up towards the patient's face.
- Press firmly on the clear portion of the enFuse to attach to abdomen.

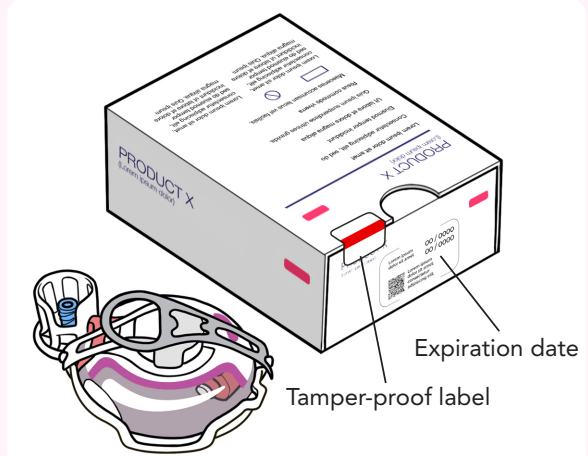
⚠ **Do not** reposition enFuse once attached to the belly. enFuse functions regardless of Fill Window orientation.

How to Store the enFuse

- Keep the enFuse unit in unopened tray inside the original box.
- Do not** open the tray until ready for the dose delivery.
- Store** the enFuse unit in clean, dry area away from heat and sunlight, at temperature 36°F-86°F (2°C-30°C).
- Use** the enFuse where the temperature is 41°F-104°F (5°C-40°C).

General Information

- enFuse is for abdominal subcutaneous delivery of medicinal products only.
- enFuse has a fill capacity of 20mL.
- Consult pharmacy label for pump fill volume and infusion duration.



Start Dose Delivery

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- Hold the enFuse with 1 hand. Use other hand to pull Red Safety Tab off.
- The dose delivery will not start until the Red Safety Tab is removed.

⚠ **Do not** use materials to hold the enFuse in place that could compress the enFuse against the patient's skin.

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- ⚠ Pushing the button will insert the needle into the patient's skin. The patient may feel the needle go into the skin.
- After placing the enFuse on abdomen, immediately press the button firmly until it stays in place to start the dose delivery.
- ⚠ Be careful not to bump, knock, or twist the enFuse or button during dose delivery.
- ⚠ **Do not** sleep or bathe during dose delivery. During dose delivery keep abdomen totally dry. Avoid intense physical activity.
- Light daily activities can be done during dose delivery.

Track Dose Delivery

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- Dose delivery will continue as long as Button is in. Delivery time will vary based on dose volume, medication viscosity, and device needle configuration. Refer to Flow Rate Table (Page 1) for estimated delivery time ranges.
- To track progress, watch the Fill Gauge move across Fill Window towards empty. Gauge is an estimate of progress. It may take some time to move and may advance slowly.
- ⚠ If dose delivery exceeds 2 hours and 30 minutes, refer to Questions and Answers.
- ⚠ **Do not** remove the enFuse until the Button pops out.
- ⚠ **Caution:** Holding down the Button will pause the flow of medicine. Dose delivery will begin again when the Button is released.
- ⚠ If the patient has an allergic reaction to the adhesive, provide or seek immediate medical care.

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- When the Button pops out, the dose delivery is done, and needle is pulled out of the skin, back into the enFuse, and will not stick you or the patient.
- ⚠ **Do not** remove the enFuse until the Button pops out. The Button popping out is the only way to know if the dose delivery is complete.

Remove Empty enFuse

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- Use thumb to lift Adhesive Tab. Hold the Adhesive Tab against the enFuse.
- Slowly peel the enFuse away from patient's skin.
- ⚠ **Do not** reuse enFuse. Refer to Questions and Answers for more information.
- ⚠ **Do not** rub injection site.

Dispose of Empty enFuse and Supplies

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- Put used enFuse in an FDA cleared sharps disposal container right away after use.
- The Transfer Base with empty syringe attached, alcohol wipe, and packaging may be placed in trash.
- Refer to organizational or local disposal policies to ensure compliance.

If you do not have a FDA cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow community guidelines for the right way to dispose of sharps disposal container.

- Do not dispose of full sharps disposal containers in the trash unless community guidelines permit this.
- Do not recycle full sharps disposal containers.
- There may be state or local laws about how you should throw away used needles and empty syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- Keep the used enFuse and sharps disposal container away from children.

Questions and Answers

Can I use more than 1 syringe to fill the enFuse?
No, use only 1 syringe per enFuse.

Can I remove the enFuse from the abdomen and put it on later to finish dose delivery?
No. enFuse cannot be reattached. If removed, the full dosage may not be delivered.

What should I do if dose delivery takes longer than 2 hours and 30 minutes?
Press and hold the button while removing enFuse from patient's skin. Put the device aside. Consult prescribing health care provider.
⚠ **Do not** touch the bottom of the enFuse as the needle will be exposed.

What if I try to re-use the enFuse?
The enFuse has been designed to lock out after delivery of the dose and cannot be re-used. The enFuse ST System cannot be re-sterilized.

Possible Complications

What if the Button won't push in and lock?
Make sure that you have taken off the Red Safety Tab. If the Safety Tab is removed, make sure you have tried to push the Button all the way in. If you still cannot push the Button all the way in, then the enFuse is damaged. Remove the enFuse and set aside. Open a new enFuse and start over.

What should I do if syringe plunger will not push down to fill the enFuse?
You must firmly press down on the plunger to fill the enFuse. It will feel like there is resistance.

What if the enFuse falls off?
If the enFuse falls off the body, pick it up carefully. Do not touch the needle or any medicine that may be on the enFuse. Put the device aside. Consult the prescribing health care provider.

Key Risks and Potential Adverse Effects

- Local injection site reactions such as local tissue inflammation, irritation, swelling, or trauma
- Minor bruising, contusion, minor puncture injury, or laceration
- Systemic Infection due to exposure to blood borne pathogens
- Increased or decreased absorption of medicinal product
- Insignificant delay in medicinal product delivery

Serious incidents regarding the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

It is normal to see a little bleeding. You may press a cotton ball or gauze on the injection site and cover it with a small bandage.

Contraindications

- Not intended to be used with lifesaving acute medications.
- Not intended to be used with products that need a carefully controlled flow rate.
- Not intended to be used on pregnant women.
- Not intended to be used with medicinal products that may cause permanent or severe harm requiring medical intervention if it comes into contact with the skin.
- Not intended for the delivery of blood, blood products, insulin, total parenteral nutrition, and lipid emulsions.
- Not intended for patients that have an acrylic allergy