

For abdominal subcutaneous delivery of ASPAVELI® Single-use On-Body Delivery System

Read these Instructions for Use before you start using the On-Body Delivery System and each time you get a new On-Body Delivery System as there may be new information. Keep these Instructions for Use after your first dose, as you may need them for future doses. The On-Body Delivery Device is placed on your body to give medicine under the skin. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. The patient or caregiver will be instructed by a qualified healthcare professional in the use of the On-Body Delivery System in accordance with the ASPAVELI Package Leaflet. The decision of a possibility of self-administration and home infusions should be made after evaluation and recommendation from the treating physician. Ask your healthcare provider about any instructions you do not understand.

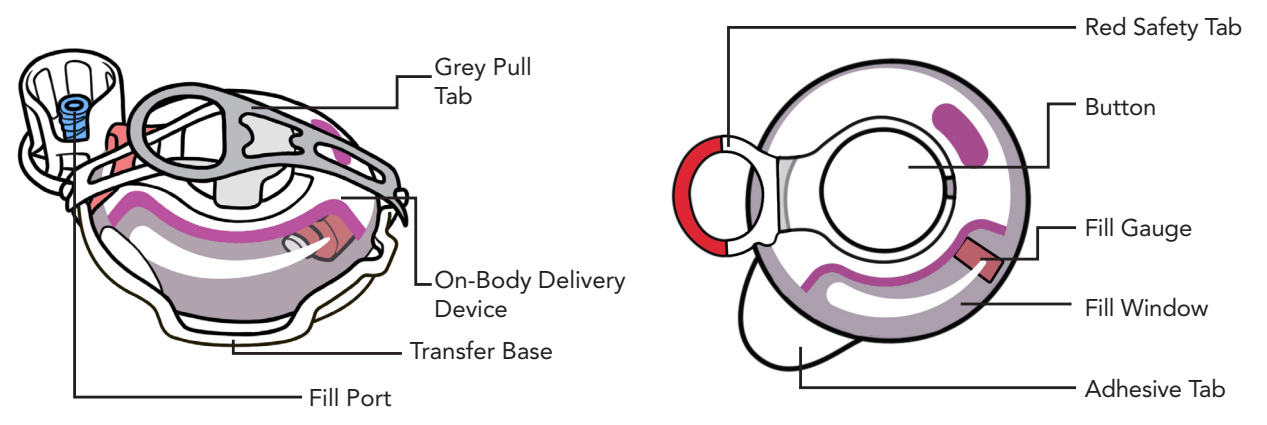
The Intended Purpose – The ASPAVELI® enFuse® On-Body Delivery System is intended for abdominal subcutaneous delivery of ASPAVELI 1 080 mg Solution for infusion.

Indications for Use – The ASPAVELI® enFuse® On-Body Delivery System is intended for abdominal subcutaneous administration of ASPAVELI 1 080 mg Solution for infusion in adolescent (age 12-17) and adult patients.

Patient Target Group(s) – Adolescents (age 12-17 and ≥ 30 kg) and Adults (age 18+) in accordance with the ASPAVELI 1 080 mg Solution for infusion product requirements.

Intended Users – Healthcare Providers (HCPs), Caregivers, and Patients (age 12+).

Parts of ASPAVELI® enFuse® On-Body Delivery System



On-Body Delivery Device in Syringe Transfer Base **On-Body Delivery Device**

Product Description:

The ASPAVELI enFuse On-Body Delivery System is a sterile, non-pyrogenic, user-filled, single-use, fixed-dose subcutaneous dose delivery system. The ASPAVELI enFuse On-Body Delivery System consists of the device (On-Body Delivery Device) and syringe transfer device (Transfer Base). The On-Body Delivery Device utilizes an elastomeric balloon to deliver the ASPAVELI medicinal product, and contains an integrated needle that is inserted into the subcutaneous space once the Button is depressed. The On-Body Delivery Device 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 On-Body Delivery Device, exposed upon removal of the On-Body Delivery Device 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 ASPAVELI upon attachment of a pre-filled, pre-measured syringe with a luer fitting (compatible with ISO 80369-7 compliant syringes). The On-Body Delivery System is fully mechanical and does not contain any electronics or software.

Clinical Benefit:

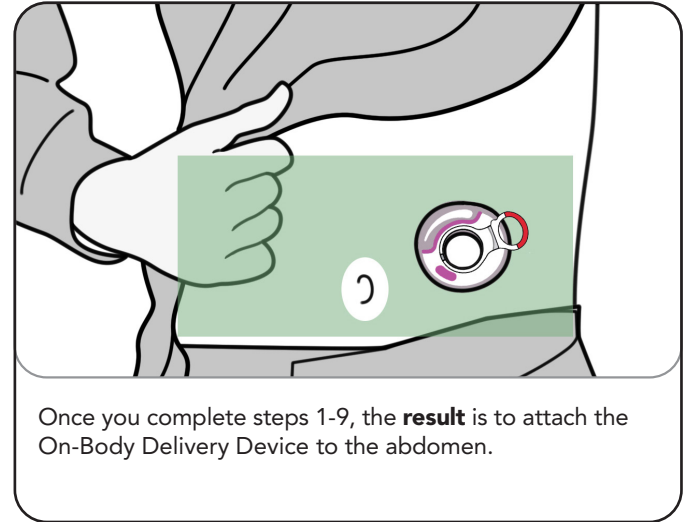
A large volume, hands-free dose administration of ASPAVELI (pegcetacoplan) to the abdominal subcutaneous space which improves patient management by reducing the burden on the user.

Warnings:

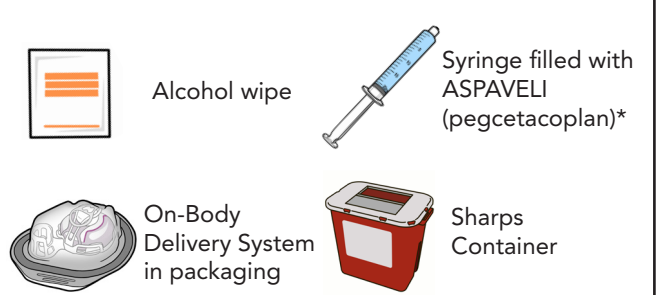
- **Warning!** Keep away from children 3 years and younger. Contains small parts.
- **Do not** use the On-Body Delivery System if tamper-proof label has been broken.
- **Do not** use if you dropped the On-Body Delivery System or if it appears damaged.
- **Do not** use if sealed plastic tray is open or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

Precautions:

- **Do not** use the On-Body Delivery System 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 On-Body Delivery Device.
- **Do not** store the On-Body Delivery System outside of storage conditions.
- **Do not** use the On-Body Delivery System outside of use conditions.
- **Do not** apply the On-Body Delivery Device along the belt line or on areas where the On-Body Delivery Device will be affected by folds in the skin.
- **Do not** remove Red Safety Tab until On-Body Delivery Device 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 the On-Body Delivery Device and 2.5 cm from last dose delivery site. Use the On-Body Delivery Device on abdomen only.
- **Do not** bathe, shower, exercise, use hot tubs, whirlpools, or saunas. Avoid getting abdomen wet. The On-Body Delivery Device is not waterproof. Water or sweat may loosen On-Body Delivery Device from skin.
- **Do not** sleep during dose delivery.
- Avoid engaging in intense physical activity.
- **Do not** bump or knock On-Body Delivery Device.
- **Do not** bump the On-Body Delivery Device Button.



Supplies required for Dose Delivery



*Refer to the ASPAVELI Package Leaflet for the instructions to prepare and fill syringe. The On-Body Delivery device will administer the transferred volume. The volume cannot be changed once filled.

Fill the On-Body Delivery Device with ASPAVELI Liquid

1

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

2

- Pick up the syringe filled with ASPAVELI (pegcetacoplan).
- **Double check** that you have withdrawn your prescribed dose.
- 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.

3

- Firmly push the syringe plunger down. The syringe plunger may be hard to push.
- Watch the Fill Gauge advance as ASPAVELI (pegcetacoplan) is pushed into the On-Body Delivery Device.

Identify and Clean the Delivery Site

4

- 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 On-Body Delivery Device is filled, continue with the preparation and dose delivery.
- **Do not** store filled On-Body Delivery Device.

5

- Determine where to place the On-Body Delivery Device on the bare abdomen.
- **Use** the On-Body Delivery Device on abdomen only.
- Choose a site:
 - At least 2.5 cm from the edge of patient’s belly button and the edge of the On-Body Delivery Device.
 - 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 On-Body Delivery Device along the belt line or on areas where the On-Body Delivery Device 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 On-Body Delivery Device.

6

- 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.

Remove the On-Body Delivery Device from Transfer Base and Attach to Abdomen

7

- 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 On-Body Delivery Device is attached to body.

8

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


9

- Position the On-Body Delivery Device so the Fill Window is pointed up towards the patient’s face.
- Press firmly on the clear portion of the On-Body Delivery Device to attach to abdomen.
- **Do not** reposition On-Body Delivery Device once attached to the belly. On-Body Delivery Device functions regardless of Fill Window orientation.

Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
	Country and 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 resterilize	Indicates a medical device that is not to be resterilized
	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 labeling
	Medical Device	Indicates that the item is a Medical Device
	Authorized representative in the European Union	Indicates the authorized representative in the European Union
	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
	Authorized representative in the United Kingdom	Indicates the authorized representative in the United Kingdom
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland
	Importer	Indicates the entity importing the medical device into the locale
	Open here	Indicates the location where the package can be opened
	MedEnvoy Switzerland c/o Cr 360 – UL International 6302 Zug Switzerland	
	Emergo Consulting (UK) Limited c/o Cr 360 – UL International Compass House, Vision Park Histon Cambridge CB24 9BZ United Kingdom	
	Emergo Europe Westervoortsedijk 60, 6827 AT Arnhem The Netherlands	
	Enable Injections, Inc. 2863 E. Sharon Road Cincinnati, OH 45241, USA	
		10132152 Rev. B Issued FEB2026

Start Dose Delivery

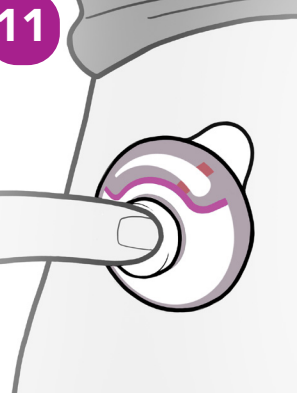
10



- Hold the On-Body Delivery Device 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 On-Body Delivery Device in place that could compress the device against the patient's skin.

11



- 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 On-Body Delivery Device on abdomen, immediately press the button firmly until it stays in place to start the dose delivery.

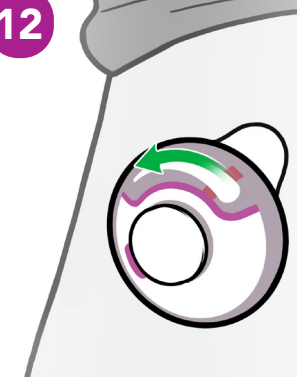
⚠️ Be careful not to bump, knock, or twist the On-Body Delivery Device or Button during dose delivery.

⚠️ **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

12



- Dose delivery will continue as long as Button is in. It may take about 30 to 60 minutes to complete.
- 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.

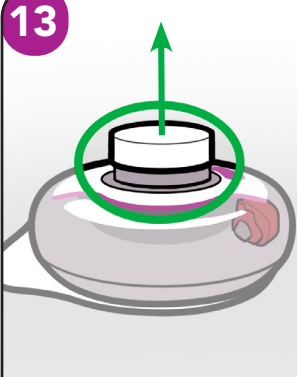
⚠️ If dose delivery exceeds 2 hours (120 minutes) refer to Questions and Answers.

⚠️ **Do not** remove the On-Body Delivery Device 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.

13

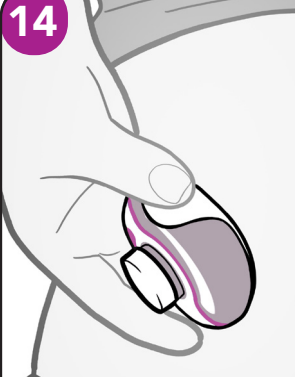


- When the button pops out, the dose delivery is complete, and the needle is pulled out of the skin—back into the On-Body Delivery Device—so it will not stick you or the patient.

⚠️ **Do not** remove the On-Body Delivery Device until the Button pops out. The Button popping out is the only way to know if the dose delivery is complete.

Remove Empty Device

14




- Use thumb to lift Adhesive Tab. Hold the Adhesive Tab against the On-Body Delivery Device.
- Slowly peel the On-Body Delivery Device away from patient's skin.

⚠️ **Do not** reuse On-Body Delivery Device. Refer to Questions and Answers for more information.

⚠️ **Do not** rub injection site.

Dispose of Empty On-Body Delivery Device and Supplies

15



- Put used On-Body Delivery Device in a sharps disposal or puncture-resistant container or dispose according to local regulations right away after use.
- The Transfer Base with empty syringe attached, alcohol wipe, and packaging may be disposed of according to local requirements.
- Keep these Instructions for Use after your first dose, as you may need them for future doses.
- Refer to organizational or local disposal policies to ensure compliance.

If you do not have a 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.

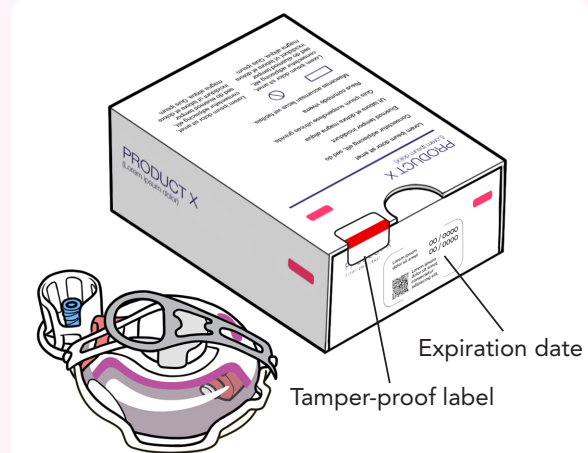
- Do not dispose of full sharps disposal containers in the trash unless community guidelines permit this.
- Do not recycle full sharps disposal containers.
- Keep the used On-Body Delivery Device and sharps disposal container away from children.

How to Store the ASPAVELI® enFuse® On-Body Delivery System

- Keep the On-Body Delivery System in unopened tray inside the original box.
- Do not** open the tray until ready for the dose delivery.
- Store** the On-Body Delivery System in clean, dry area away from heat and sunlight, at temperature 2°C - 30°C.
- Use** the On-Body Delivery System where the temperature is 5°C - 40°C.

General Information

- The On-Body Delivery Device is for abdominal subcutaneous delivery of pegcetacoplan only.
- On-Body Delivery Device has a fill capacity of 20 mL.
- Consult pharmacy label for fill volume and drug delivery duration.



Questions and Answers

Can I use more than 1 syringe to fill the On-Body Delivery Device?
No, use only 1 syringe per On-Body Delivery Device.

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

What should I do if dose delivery takes longer than 2 hours?

Press and hold the button while removing the On-Body Delivery Device from patient's skin. Put the On-Body Delivery Device aside. Consult the prescribing medical doctor.

⚠️ **Do not** touch the bottom of the On-Body Delivery Device as the needle will be exposed.

What if I try to re-use the On-Body Delivery Device?

The On-Body Delivery Device has been designed to lock out after delivery of the dose and cannot be re-used. The On-Body Delivery 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 On-Body Delivery Device is damaged. Remove the On-Body Delivery Device and set aside. Open a new On-Body Delivery System and start over.

What should I do if syringe plunger will not push down to fill the On-Body Delivery Device?

You must firmly press down on the plunger to fill the On-Body Delivery Device. It will feel like there is resistance.

What if the On-Body Delivery Device falls off?

If the On-Body Delivery Device falls off the body, pick it up carefully. Do not touch the needle or any medicinal product that may be on the On-Body Delivery Device. Put the On-Body Delivery Device aside. Consult the prescribing medical doctor.

Other Potential Risks

- 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

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.