TERUMO SYRINGE with Fixed Needle 1 ml

1 mg/0.2 ml leuprolide acetate

Instructions for Use ENGLISH

SYMBOL EXPLANATION

LOT	Batch code		Do not re-use	MD	Medical Device
REF	Catalogue number		Do not use if package is damaged and consult instructions for use		Non pyrogenic
	Consult Instructions for Use		Fragile, handle with care		Single Sterile Barrier System
#	Contents		Keep away from sunlight	STERILE EO	Sterilized using ethylene oxide
	Date of Manufacture		Keep dry	2°C 30°C	Temperature limit
	Do not resterilize		Manufacturer		Use-by date
Rx only	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician				

PRODUCT DESCRIPTION

Non-Toxic

Needle Gauge	Needle Length	Needle Outer Diameter	Needle Length	Wall Thickness	Syringe Nominal Capacity/ Nominal Volume (v)	Dead Space Volume
27G	1/2"	0.4 mm	12 mm	Regular Wall (RW)	1 ml	0.01 ml

Tolerance on Graduated Capacity		
Syringe Nominal Capacity/ Nominal Volume (v)	**When syringe filled to a volume less than half of the nominal capacity**	**When syringe filled to a volume equal or greater than half of the nominal capacity**
1 ml	± (1.50% of v + 2% of expelled volume)	2% of expelled volume

INTENDED PURPOSE

TERUMO SYRINGE with Fixed Needle for 1 mg/0.2 ml leuprolide acetate is a hypodermic syringe intended for manual aspiration of leuprolide acetate and for the injection of this solution into parts of the body below the surface of the skin.

INDICATIONS

The device is indicated for subcutaneous injection of leuprolide acetate in the palliative treatment of advanced prostatic cancer.

CONTRAINDICATIONS

No contraindications.

PATIENT TARGET GROUP

Men with advanced prostatic cancer.

INTENDED USERS

Healthcare professional or lay person.

CLINICAL BENEFIT

The device has an indirect clinical benefit (indirect medical effect) since it is used for subcutaneous injection of leuprolide acetate in the palliative treatment of advanced prostatic cancer.

WARNINGS

- Do not use if unit package is damaged.
- Use immediately after opening the unit package.
- For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- The needle is made of stainless steel containing nickel and cobalt. Cobalt is classified as CMR* 1B and is present in a concentration above 0.1% weight by weight. Current scientific evidence supports that medical devices manufactured from stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

*CMR = Carcinogenic, mutagenic or toxic to reproduction (CLP Regulation EU 1272/2008)

PRECAUTIONS

- The syringe is intended for use immediately after filling, as it is not suitable for containing fluids over extended periods of time.
- If the needle is bent or damaged, no attempt should be made to straighten the needle or use the product.
- After use, dispose of safely as medical waste in a sharps disposal container and/or according to health institution policies. The product is biohazardous and is physically hazardous due to its sharp edge.

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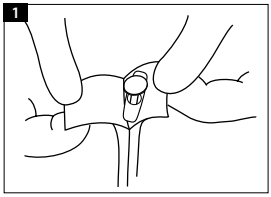
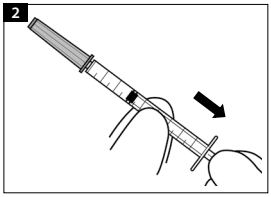
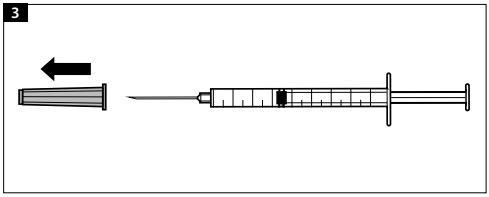
DIRECTIONS FOR USE

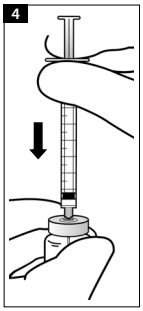
Aseptic technique, proper skin preparation and continued protection of the site are essential. Observe Universal Precautions on ALL patients. **PRECAUTION** Handle with care to avoid needle sticks. Keep hands behind the needle at all times during use and disposal.

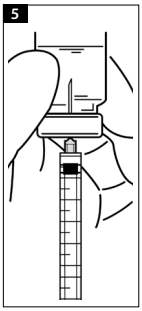
1. Open the blister package.
2. Pull the syringe plunger back to the graduation line for the prescribed dose. This fills the syringe with air.
3. Remove the cap. Do not touch the needle.
4. Place the bottle on a clean, flat surface and push the needle through the center of the rubber stopper on the bottle. Push the plunger all the way in to inject air into the bottle.
5. Keep the needle in the bottle. Lift the bottle and turn it straight upside down. Check to see that the needle tip is in the solution.
6. With the needle tip in the solution, slowly pull back the plunger until the syringe fills to the graduation line for the prescribed dose. If any air bubbles appear in the syringe, remove them by pushing the plunger up slowly. With the needle tip still in the solution, pull the plunger back until it is once more at the graduation line for the prescribed dose.
7. Perform injection procedure according to established technique.
8. Do not re-cap.
9. Dispose of safely.

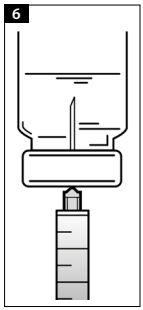


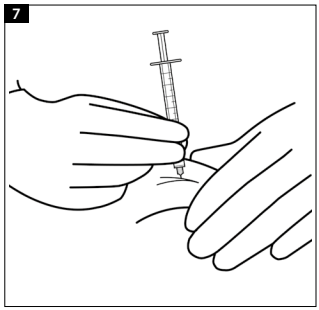


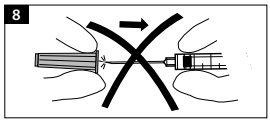


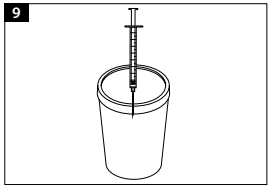












PRECAUTIONS FOR STORAGE

Store between 2°C and 30°C. Keep dry. Keep away from sunlight. Fragile, handle with care.

REPORT OF INCIDENT

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

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Made in Belgium

For safety and performance information, please visit safetyinfo.terumo-europe.com