Instructions for use

PRODUCT NAME: ***INFUSION SET FOR SINGLE USE***

BRAND NAME: ***CHIRAPLUS - P / CHIRAPLUS - G***

INTENDED PURPOSE:
- Infusion set for single use is intended for administration liquids and drugs into the circulation system by using of intravenous catheters and cannulas.

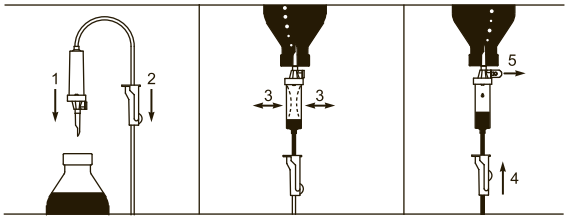
INTENDED USERS:
- Health care professionals with relevant knowledge of use these types of medical devices. Infusion sets are simple and well-known products.

INTENDED PATIENT POPULATION:
- The type of Infusion set for single use containing phthalates should not be used for treatment of pregnant or nursing women, infants and children.

CONTRAINDICATIONS:
- Not to be used other than as indicated in intended purpose.
- Administration of highly viscous fluids.
- Blood Transfusion.

INSTRUCTIONS FOR USE:
- Remove Infusion set from unit package, closed the roller clamp with flow regulator.
- Prepare container with infusion fluid.
- Remove protector from piercing spike. Insert the spike to its full lenght into the top of the Infusion fluid container. Suspend/hang the container.
- Squeeze the drip chamber and set fluid level.
- Hang the connector end in the groove provided in the roller clamp.
- Open the airvent cap of piercing spike.
- Open the clamp. The fluid starts running into the tubing and priming takes automatically up to the connector end. Close the clamp.
- Remove protective cap from the connector end and connect with venous access device.
- Open roller clamp and adjust flow of infusion with flow regulator.

CAUTIONS:
- Read instructions before use. The product should be used according to the Instructions for use.
- Check the product and package integrity prior to use and also the expiry date.
- Do not use if protective cap is loose or missing.
- Do not use if package is opened or damaged.
- For pressure or gravity feed, as marked on product packaging (G = Gravity, P=Pressure).
- Use the product immediately after opening the individual blister packing.
- Close the airvent during periods of interrupted infusion therapy.
- Do not re-sterilize. Discard the set after single use.
- This product contains phthalates **(DEHP)**; as marked with symbol PHT DEHP.
- This product contains phthalates DEHP. The plasticizer DEHP is present in the fluid pathway of the Infusion set tubing. Leaching of DEHP is possible on contact with lipids by administering lipophilic drugs. Lipophilic drugs should not be administered with this type of infusion set during the treatment of pregnant or nursing women, infants and children.
- Infusion set with Flashball contains LATEX and is marked with symbol LATEX.
- Reuse and cleaning of the product may alter their structural and mechanical properties. It may lead to infections or other illness/injury.
- The device should be replaced and dispose as per facility approved protocol or guidelines.
- Store at 0-40°C temperature, avoid excessive heat, protect from direct sunlight and moisture.
- **CHIRANA T. Injecta** will not responsible for any direct incident or consequential damages resulting from reuse or improper use of the product.
- Report any health incident associated with medical device to healthcare professional or manufacturer.



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CHIRANA T. Injecta

Fragile, handle with care

Keep away from sunlight

Keep dry

CE 2265 This product meets the requirements of the Regulation 2017/745

Caution

Consult instructions for use

Do not re-use

Do not resterilize

Do not use if package is damaged

REF Cataloque number

LOT Batch code

Date of manufacture

Use-by date

STERILE EO Sterilized using ethylene oxide

Single sterile barrier system

Single sterile barrier system with protective packaging outside

Distributor

0°C 40°C Temperature limit

Manufacturer

Non-pyrogenic

PHT DEHP Contains or presence of phthalate

Contains hazardous substances

LATEX Contains or presence of natural rubber latex

LATEX LATEX Free

15 µm Liquid filter with pore size

20 ml Drops per mililitre

UDI Unique device identifier

MD Medical device

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