

Tiritas® EFFECT Ampollas pequeñas/ Bolhas pequenas; Tiritas® EFFECT Ampollas grandes/ Bolhas grandes; Tiritas® EFFECT talón/ no calcanhar; Tiritas® EFFECT Especial ampollas / Especial bolhas

General Product Description

Tiritas EFFECT Ampollas talón / Bolhas no calcanhar and Tiritas EFFECT Ampollas pequeñas / Bolhas pequenas presentations are composed of a layer of 300 µm / 0,3 mm hydrocolloid material acting as the wound pad, another larger layer of 300 µm / 0,3 mm hydrocolloid material acting as the dressing backing material, the silicone paper protection in contact with the adhesive coated side of the dressing and the peel pack (individually sealed plaster).

Tiritas EFFECT Ampollas grandes / Bolhas grandes presentations are composed of a layer of 600 µm / 0,6 mm hydrocolloid material acting as the wound pad, another larger layer of 100 µm / 0,1 mm hydrocolloid material acting as the dressing backing material, the silicone paper protection in contact with the adhesive coated side of the dressing and the peel pack (individually sealed plaster).

All individually sealed plasters (one plaster in each peel pack) are packed in a labeled plastic box, which includes a leaflet with instructions for use.

Tiritas EFFECT Especial ampollas / Especial bolhas presentations contains in the same plastic box: Tiritas EFFECT Ampollas talon / Bolhas no calcanhar and Tiritas EFFECT Ampollas pequeñas / Bolhas pequenas.

Intended Purpose

Hydrocolloid plasters are non-active, single-use, self-adhesive, non-sterile devices consisting of a self-adhesive hydrocolloid wound contact layer and an adhesive coated backing material (carrier material), protected with a silicone paper, for the protection and treatment of blisters.

The products are intended for humans, without restrictions (in age group, weight range, health status or condition), for use by lay-users, in contact with intact skin (healthy skin) and breached skin, and short-term (60 minutes ≤ Duration ≤ 30 days, acc. to MDR) / prolonged use (24 hours < Duration ≤ 30 days, acc. to ISO 10993-1:2018) duration of use.

The products do not contain resorbable components, medicinal products / drug substances (derived from human blood or plasma or not), tissues or cells of human or animal origin, radioactive substances, nanomaterials or other hazardous components (besides latex in the peel-pouch's adhesive of some Private Label presentations).

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Application/Indication

- Wash hands and ensure the affected area is clean, dry and oil free before applying the plaster.
- Open the peel pack and extract the plaster.
- Warm the plaster with the hands before applying.
- Remove the first protective paper and apply the exposed part of the plaster to the affected skin area.
- Then gently pull the second protective paper and apply the rest of the plaster. Gently mould the plaster edges to ensure optimum adhesion.
- The application maximum of the hydrocolloid is up to 4 days per individual product. Should you wish to remove the plaster early, first wet it briefly with warm water.

Reference Numbers

Ref no.	Description	Length	Content of folding box
5360447	Tiritas EFFECT XL blister	75x45 mm	P6
5360147	Tiritas EFFECT Talón	76x45 mm	P5
5360347	Tiritas EFFECT Blister small	19x55 mm	P6
5360517	Tiritas EFFECT Blister Mix	76x45 mm & 19x55 mm	P7

If applicable: Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

The hydrocolloid plasters must not be used on non-treated infected blisters, major injuries, highly bleeding or exudative wounds or for pressure ulcers or any other use apart from the mention in the intended use section.

Adverse reactions may occur in patients who are allergic or hypersensitive to the product components.

All presentations:

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- Only apply the plaster if the hydrocolloid pad completely covers the blister/minor injury/corn/cold sore/abrasion.
- In cases of diabetes mellitus always consult a doctor before using plasters.
- Do not apply the product for more than 4 days.
- Store plasters in a cool (not in the fridge), dry place, out of the reach of children.

All presentations except Cold sore presentations:

- Consult a doctor before applying the plaster on a potentially infected blister, minor injury, or if the blister or minor injury shows signs of infection while plasters are in place (e.g. redness, overheating, swelling or pain).

Specially for Blister presentations:

- Do not burst a sealed blister as this could risk an infection.

Single Use Device

Reusing a disposable and single-use medical device is dangerous and it could cause risk of infection. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Tiritas® EFFECT Ampollas pequeñas/ Bolhas pequenas; Tiritas® EFFECT Ampollas grandes/ Bolhas grandes; Tiritas® EFFECT talón/ no calcanhar; Tiritas® EFFECT Especial ampollas / Especial bolhas should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); 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/or its authorised representative and to your national authority.

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Product Performance /Material Characteristics

Hydrocolloid 300 µm/0,3 mm

Property	Test method	Unit	Requirements
Peel adhesion on Steal Plates (90°)	TM00 0090-04	N/25mm	6,9 (+2,7 / -4,1)

Hydrocolloid 600 µm/0,6 mm

Property	Test method	Unit	Requirements
Peel adhesion on Steal Plates (90°)	TM00 0090-04	N/25mm	8,4 (+2,7 / -4,9)

Labelling

Lot-No. with 9-Digit Code

e.g.:



0XXX

Year and number of production

XX

Week of production

12X

For internal purposes only

Manufacturing Date

e.g.:


2020
year

01
month

07
day

Use-by-Date

e.g.:


2023 - 01
year month

Shelf Life: 3 years

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Medical Device



Unique Device Identification (UDI)



Distributor



Latest Date of Revision: 2020-03-12