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Belotero Russland SOFT GA MN 33796	Format: 300x210 mm	MZ 000 / AZ 00000		
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BELOTERO® SOFT

GB INSTRUCTIONS FOR USE LEAFLET FOR BELOTERO® SOFT
 RUS ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ ПРЕПАРАТА БЕЛОТЕРО СОФТ.

GB INSTRUCTIONS FOR USE LEAFLET FOR BELOTERO® SOFT

Description
 BELOTERO® Soft is a sterile, apyrogenic, viscoelastic, clear, colourless transparent, isotonic gel. BELOTERO® Soft consists of cross-linked sodium hyaluronate from bio fermentative origin.

Presentation
 BELOTERO® Soft is presented in a 1 ml glass syringe for single use, sterilised by moist heat by autoclave. Each syringe is supplied with 2 30G1/2 sterile needles (the product is in a combined packaging carrying the CE mark) and 2 traceability labels.

Composition
 Cross-linked sodium hyaluronate: 20 mg/ml
 Phosphate buffer pH 7 q.s.: 1 ml

Indications
 BELOTERO® Soft is an injectable implant indicated for use to increase the volume of skin tissue which enables:

- to correct shallow facial depressions either of accidental origin, or age-related (scars, fine lines, crow's feet wrinkles)
- to retouch a correction undertaken with BELOTERO® Basic, immediately or a few weeks after the first injection.

Dosage and method of administration
 BELOTERO® Soft is designed to be injected into the superficial or middle dermis by a legally certified practitioner. For successful treatment it is essential that the practitioner has received prior training in the injection technique for increasing the volume of skin tissues.

BELOTERO® Soft must be injected into healthy, non-inflamed, disinfected skin. Screw the sterile 30G1/2 needle onto the Luer Lock tip, holding the Luer Lock. Remove the protective needle sheath turning it in the same direction as the direction used to fix the needle. Start the injection pointing the needle cutting blade downwards.

BELOTERO® Soft may be injected into the superficial or middle dermis using the multi-injection, linear retracing or blanket injection techniques. In the latter of these cases, BELOTERO® Soft should be used in conjunction with BELOTERO® Basic, the BELOTERO® Soft being injected into the superficial layers of the dermis after injection of BELOTERO® Basic into the deeper layers of the skin. If the needle becomes blocked and the injection pressure becomes too great, stop the injection and change the needle. Over-correction is not necessary. After the injection, massage gently in order to distribute the product uniformly.

Contra indications
 BELOTERO® Soft is contra indicated:

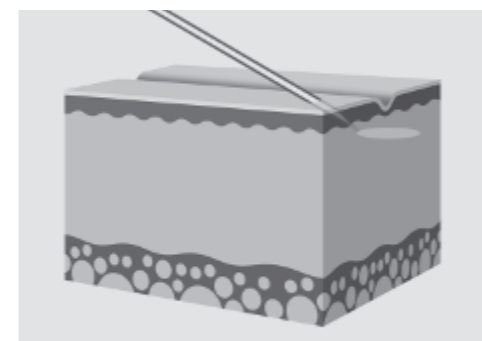
- in cases of hypersensitivity to hyaluronic acid,
- in cases of auto immune disease or diabetes,
- in cases of recurrent sore throat,
- in cases of acute joint rheumatism,
- in cases of Osler-rendu endocarditis,
- in patients pre-disposed to cheloid scarring,
- in pregnant or breast-feeding women,
- in young people less than 18 years old.

Do not inject BELOTERO® Soft into blood vessels.
 Do not inject BELOTERO® Soft into rings around the eyes.
 Do not use BELOTERO® Soft to increase the volume of the breasts.
 Do not use BELOTERO® Soft in the bones, tendons, ligaments or muscles.

BELOTERO® Soft must not be used in one treatment session in association with other aesthetic medicine techniques such as peeling, dermabrasion or any types of laser treatment, but at the earliest after complete healing of such treatment. In all cases, even if healing occurs earlier, BELOTERO® Soft must not be used earlier than 2 weeks after the last treatment. There is no experience for the combination of BELOTERO® Soft with the above mentioned treatments.

Precautions for use
 Before treatment the patient must be informed about the device, its contraindications and possible side effects.
 Before use, confirm the status of the individual sterility protector and the expiry date both for the syringe and for the needle. Do not use these products if the expiry date has lapsed or if the sterility bag is opened or damaged.

Sodium hyaluronate precipitates in the presence of quaternary ammonium salts (such as benzalkonium chloride). It is therefore recommended that BELOTERO® Soft does not come into contact with such substances.



Injection of Basic into the middle to deep layers of the dermis.
 Рис.1. Введение Белотеро Софт в поверхностные или средние слои дермы

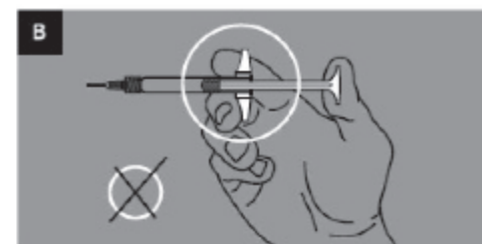
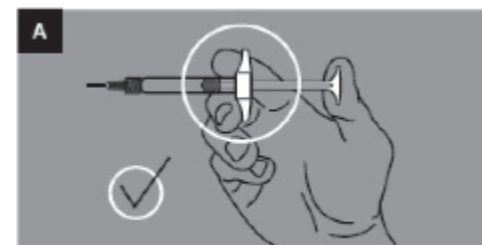


Рис.2. Положение шприца в руке

Consumer Care	Freigabe	Freigabe nach Korrektur	Neuvorlage nach Korrektur	Datum, Unterschrift
Produktmanager	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Leitung Marketing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Forschung u. Entwicklung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Arzneimittelzulassung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rechtsabteilung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Geschäftsleitung	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

