



XanterDES



Hydrating and lubricating sterile ophthalmic solution

Xanthan gum 0.2% and desonide sodium phosphate 0.025%

Composition

Xanthan gum 0.2%, desonide sodium phosphate 0.025%, monobasic sodium phosphate monohydrate, disodium phosphate dodecahydrate, sodium citrate, purified water.

Presentation

20 single-dose containers, 0.3 ml each and 1 leaflet

Indications

XANTERDES is indicated to relieve eye discomfort and irritation due to environmental conditions such as dust, heat, smoke, wind, air conditioning, allergens.

XANTERDES also contains, as ancillary substance, a very low concentration of a corticosteroid, desonide sodium phosphate, which can be useful in case of redness of the ocular surface, as for example in ocular dryness.

Characteristics and mode of action

XANTERDES gently provides hydrating and lubricating action to the eye surface due to the presence of a natural polymer, xanthan gum.

XANTERDES, after application into the conjunctival sac, it integrates with the tear restoring the normal lubrication of the ocular surface.

The presence of desonide sodium phosphate is to be considered ancillary to the main lubricant action of **XANTERDES** and helps to reduce ocular redness that may occur during mild eye inflammatory processes.

XANTERDES is preservative-free.

Dosage and administration

It is recommended to instill 1 drop of **XANTERDES** in the conjunctival fornix, three times a day, unless otherwise indicated by a doctor.

Instructions for use

1. Make sure that the single-dose container is intact before use.
2. Tear one single-dose container from the strip.
3. Hold the single-dose container upright (with the cap pointing upwards) and twist off the cap, without pulling it.
4. Instill **XANTERDES** into the eye(s). Do not let the open-end of the single-dose container touch your eye or anything else.



Contraindications

Hypersensitivity to the products' components; ocular hypertension and glaucoma, eye infections (such as Herpes Simplex, corneal virus infections, bacterial, viral or fungal conjunctivitis, tuberculosis and mycosis of the eye, purulent and herpetic blepharitis, sty), lesions or corneal abrasions; diseases related to corneal thinning.

Warnings

The product contains low concentrations of corticosteroids therefore should not be used chronically, unless otherwise indicated by the doctor.

Cases of corneal calcification have been very rarely reported in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

The use, especially if prolonged, of corticosteroids may cause an increase of the intraocular pressure. It is therefore advisable to monitor intraocular pressure if corticosteroids are used for more than two weeks. Since corticosteroids also favor the onset of cataracts, it is advisable not to use them for long periods of time.

Pregnancy, lactation

In childhood and in pregnancy, the product should be administered in cases of real need and only under medical supervision.

Adverse reactions

The use of the product may occasionally cause mild burning after instillation.

Interactions with other drugs or medical device for ocular use

Product interactions with the administration of other ophthalmic drugs are unknown. However, it is advised not to administer other drugs or medical devices for ocular use within 10 minutes from the instillation of **XANTERDES**. It is not necessary to remove the contact lenses before the administration of **XANTERDES** since the product does not alter the physical characteristics, including the transparency, of the most common soft, semirigid and rigid contact lenses.

Precautions for use and storage



Do not use **XANTERDES** if single-dose container is opened or damaged.

Avoid touching the eye or any surface with the tip of the opened container and do not allow the tip of the container to touch the eye. Each single-dose container must be used immediately after opening.

Any residual product should not be re-used, since **XANTERDES** does not contain preservative and the remaining product may become contaminated.

After the opening of each aluminum sachet, the remaining single-dose containers must be kept inside the sachet to protect the product from light. After aluminum sachet opening, the single-dose containers should be used within 28 days.

Do not store above 25 °C.

Do not use **XANTERDES** after the expiry date.

Do not dispose the product in the environment after use.

It would be advisable to eliminate the vial and any residual product as special waste. For the correct disposal of the product, please follow the national or local regulations.

The administration of **XANTERDES** to children or people with limited skills should be supervised by a responsible adult.

FOR TOPICAL OCULAR USE ONLY - KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

The product must be used under medical advice.

Notification of adverse reactions

Any adverse reactions should be reported to the local Vigilance Authorities or to:

SIFI S.p.A. - Via Ercole Patti, 36 - 95025 Aci Sant'Antonio (CT) Italy
– e-mail: vigilance@sifigroup.com

Summary of safety and clinical performance (SSCP) of the medical device

The Summary of safety and clinical performance (SSCP) of **XANTERDES** is available at the following URL: <https://ec.europa.eu/tools/eudamed>.

Manufacturer:

SIFI S.p.A. – Via Ercole Patti, 36 - 95025 Aci S. Antonio (CT) – ITALY

XANTERDES is a sterile medical device.



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Last revision of the text: October 2022

Detailed and updated information on this medical device is available by scanning the QR code that appears in the instructions for use and the carton box with a smartphone. The same information is available at the following URL: <https://qr.sifigroup.com/1G868680/>



Simboli - Symboles – Symbols - Simbolos - Simboluri

	Fabbricante Fabricant Manufacturer Fabricante Producător	 25°C	Limite superiore di temperatura 25°C Limite supérieure de température 25°C Upper limit of temperature 25°C Limite superior de temperatura 25°C Limita superioară de temperatură 25°C
	Distribuito da Distribué par Distributed by Distribuido por Distribuit de		Non utilizzare se il contenitore è danneggiato Ne pas utiliser si le récipient est endommagé Do not use if package is damaged No utilizar si el envase está dañado A nu se utiliza dacă ambalajul este deteriorat
	Sterilizzato mediante processo asettico Stérilisé en utilisant une technique aseptique Sterilized using aseptic processing technique Esterilizado utilizando técnicas de procesado aséptico Sterilizat utilizând tehnica de prelucrare aseptică		Dispositivo medico Dispositif médical Medical device Producto sanitario Dispozitiv medical
	Numero di lotto Numéro de lot Batch code Código de lote Cod lot		Consultare le istruzioni per l'uso Consultez le mode d'emploi Consult instructions for use Consulte las instrucciones de uso Consultați instrucțiunile de utilizare
	Mese ed anno di fabbricazione Mois et à l'année de fabrication. Month and year of manufacture Año y mes de la fabricación Luna și anul producției		QR code
	Utilizzare entro AAAA-MM- Date de péremption AAAA-MM- Use by YYYY-MM - Fecha de caducidad AAAA-MM - A se utiliza până la data de AAAA-LL		Contiene una sostanza medicinale Contient une substance médicinale Contains a medicinal substance Contiene un medicamento Conține o substanță medicamentoasă
	Non riutilizzare Ne pas réutiliser Do not reuse No reutilizar A nu se reutiliza		Identificativo unico del dispositivo Identifiant unique de l'appareil Unique device identifier Identificador único de producto Identificator unic al dispozitivului