OPTIVE FUSION™ UD

INSTRUCTIONS FOR USE

Intended Purpose and Indications
OPTIVE FUSION™ UD is intended to lubricate and hydrate the surface of the eye(s) and is indicated to help provide temporary relief of dryness, irritation, burning, discomfort and/or any other symptoms caused by dry eye disease (DED) or environmental factors.

Contents of the packaging
OPTIVE FUSION™ UD is packaged within a plastic vial, with an insert, and then in a card carton.
OPTIVE FUSION™ UD solution contains sodium carboxymethylcellulose 0.5%, glycerin 1.0%, sodium hyaluronate 0.1%, levocarnitine, erythritol, sodium lactate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, purified water and hydrochloric acid or sodium hydroxide for pH adjustment. Product does not contain any preservatives.

Clinical Benefits
OPTIVE FUSION™ UD provides instant soothing relief of the feeling of dryness, irritation, burning, discomfort and/or any other symptoms caused by dry eye disease (DED) or environmental factors.

Performance Characteristics
OPTIVE FUSION™ UD can:

- Reduce eye discomfort, eye dryness and eye irritation
- Improve clinical signs of dry eye disease and tear film stability

OPTIVE FUSION™ UD is safe for use on the ocular surface in general and can be used repeatedly as needed, without any minimal time interval between two instillations.
OPTIVE FUSION™ UD is compatible with all types of lens materials (soft and rigid gas-permeable contact lenses).
OPTIVE FUSION™ UD is free of preservatives and well tolerated by patients with sensitive eyes and can be used by post-operative users (e.g. following LASIK surgery).

Target Patient Population and Intended Users
OPTIVE FUSION™ UD is an over-the-counter (OTC) ophthalmic product that is intended to be used by lay persons who may experience dryness, irritation, burning, discomfort and/or any other dry eye symptoms and does not require specific training for application.

The device has no restrictions on the target treated population, except the one listed in the Contraindications. However, safety and effectiveness have not been demonstrated in pediatric

patients. There are no specific study data on the use of the products during pregnancy and lactation in humans.

Contraindications

OPTIVE FUSION™ UD is contraindicated in patients with hypersensitivity to any ingredients in this product.

Warnings and Precautions

- Do not swallow solution.
- To avoid contamination or possible eye injury, do not touch vial tip on any surface, and avoid direct contact with the eye.
- Keep out of the reach of children.
- Do not use if solution changes color or becomes cloudy.
- Do not use after expiry date marked on the product.
- For single use only.
- Do not use if the unit dose vial is damaged
- Store at or below 25°C.
- Allow 5 minutes between the administration of other ophthalmic products.
- Keep unused product in pouch.
- Keep away from sunlight.
- This product is not intended to be re-used and should be discarded immediately after initial use.
- This product is preservative free and should be used immediately after opening to avoid contamination which could result in eye infections.
- Discontinue use and consult a doctor if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens.
- May cause transient blurring of vision which may impair the ability to drive or operate machines. The patient should wait until their vision has cleared before driving or using machinery.

Undesirable Side-Effects

OPTIVE FUSION™ UD clinical studies and post-marketing experience have identified the following residual risks:

- Eye irritation, Conjunctival hyperaemia, Eye redness, Foreign body sensation in eye, Erythema of eyelid, Blepharitis, Abnormal sensation in eye, Eye pain, Vision blurred, Punctate keratitis, Diffuse lamellar keratitis, Eye pruritus
- Superficial injury of the eye

Directions

- Ensure the vial is intact
- To open completely twist off the tab
- Place 1 or 2 drops in the affected eye(s) as needed
- Store unused vials in the original carton
- Store unused vials in the pouch
- Discard any remaining solution, and dispose of the container properly after use
- If used for post-operative care (e.g., following LASIK surgery), it is recommended for the patient to follow their eye doctor's instructions.
- Any unused product or waste material should be disposed of in accordance with local regulation. No special requirements for disposal.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

To contact the Ministry of Health:
Oman:
Department of Pharmacovigilance and Drug information
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, Sultanate of Oman

- Phone No: +968 22357687/ +968 22357686
- Fax: +968 22358489
- Email: pharma-vigil@moh.gov.om
- Website: www.moh.gov.om

UAE:
Drug department
Ministry of Health and Prevention
Pharmacovigilance & Medical Device section
• E-mail: pv@mohap.gov.ae
• P.O.Box :1853
• Tel:80011111
Dubai

Kuwait:
Ministry of Health
Drug & Food Control

- E-mail: health@moh.gov.kw
- Tel: +965 2487 7422 or +965 24877152
- Fax: +965 24865414

Qatar
Ministry of Public Health
Doha-Qatar

- P.O.Box: 42
- Phone: +97444070000
- www.moph.gov.qa

To contact AbbVie Biopharmaceuticals GmbH:
United Arab Emirates, Oman, Qatar:
Hotline: +971 56 413 5746
Email: PV.MEA@abbvie.com

Kuwait:
Hotline: +965 22052024
Email: PV.MEA@abbvie.com

How supplied

OPTIVE FUSION™ UD is supplied in 30 pack of 0.4 mL unit dose vials, and each carton contains vials of the product, and an insert with instructions for use.

Legal Manufacturer
ALLERGAN SALES, LLC
2525 Dupont Drive
IRVINE CA 92612
United States

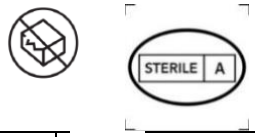
EC REP
ALLERGAN PHARMACEUTICALS
INTERNATIONAL LIMITED
Clonshaugh Business & Technology Park
Dublin 17
D17 E400
Ireland

AbbVie Logistics B.V.,
Zuiderzeelaan 53,
Zwolle,
8017 JV,
Netherlands

CE 0344

Made in Ireland By
Allergan
Pharmaceuticals
Ireland
Castlebar Road
Westport, Co. Mayo
Ireland

devices.abbvie.com



Manufacturer	***Notified Body***	***Safety Sign Attention: retain instructions for use***	***Single sterile barrier system***
EC REP ***Authorized Representative***	***Do not use if package is damaged or opened***	***Refer to instruction manual/booklet***	STERILE A ***Combined signal barrier system and aseptic sterilization (for space reasons)***
Importer	***Single Use***	***Expiry date (YYYY-MM-DD or YYYY-MM)***	***Keep away from sunlight***
Manufacturer's IFU website	MD ***Medical Device***	LOT ***Lot number***	STERILE A ***Aseptic Sterilization***
REF 11002X	***Do not resterilise***	***Date of Manufacture(YYYY-MM-DD or YYYY-MM)***	UDI ***Unique Device Identifier (01) Device Identifier (10) Lot number (17) Expiry date (YYMMDD)***

This leaflet was last revised in Oct 2022.