OPTIVE Fusion™ MD

INSTRUCTIONS FOR USE

Intended Purpose and Indications

OPTIVE FUSION™ MD 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™ MD is packaged within a plastic bottle and a cap with tip, with an insert, and then in a card carton.
OPTIVE FUSION™ MD solution contains sodium carboxymethylcellulose 0.5%, glycerin 0.9%, sodium hyaluronate 0.1%, boric acid 0.7%, sodium borate decahydrate 0.2%, erythritol, sodium citrate dihydrate, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, purified water, hydrochloric acid or sodium hydroxide for pH adjustment and is preserved with PURITE® 0.01%.

Clinical Benefits

OPTIVE FUSION™ MD 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™ MD can:

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

OPTIVE FUSION™ MD 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™ MD is compatible with all types of lens materials (soft and rigid gas-permeable contact lenses).

Target Patient Population and Intended Users

OPTIVE FUSION™ MD 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™ MD 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 bottle 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
- Do not use if packaging shows evidence of tampering
- Do not use bottle if the tamper proof seal on the bottle neck is broken before you first use it
- Close the bottle tightly immediately after use
- Discard any remaining solution 90 days after opening
- Store at or below 25 °C
- Allow 5 minutes between the administration of ophthalmic products
- Discontinue use of the product 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
- Boron has been associated with adverse reproductive effects in animals at high doses. The product contains 0.7% w/w of boric acid and 0.2% w/w of sodium borate decahydrate with total exposure to Boron from boric acid and sodium borate decahydrate less than 1 mg boron/day which is less than the permissible daily exposure for adults and children and significantly lower than levels resulting in adverse effects in animals. Consult your doctor or healthcare specialist for medical advice in relation to product use while pregnant or lactating/breastfeeding

Undesirable Side-Effects

OPTIVE FUSION™ MD clinical studies and post-marketing experience have identified the following undesirable side effects:

- Eye pain, Eye discharge, Eye irritation, Eyelid edema, Foreign body sensation in eye, Lacrimation increased, Eye swelling
- Hypersensitivity

Directions

- Do not use if packaging shows evidence of tampering

- Place 1 or 2 drops in each affected eye as needed
- Re-cap after use
- Bottle should be kept tightly closed when not in use
- 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
Durg & 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

Lebanon:

Ministry of Public Health-Service of Pharmacy

- Address: Facing Sports City – Next to Ogero, Bir Hassan, Beirut – Lebanon
- Tel +9611830300 Ext 540
- Email address: pharmacydpt@moph.gov.lb

Jordan:

Pharmacovigilance department

- Address: Shafa Badran, Ahmad Qteshat st., 11181/811951, Amman/Jordan
- Email: jpc@jfda.jo
- + 962-6-5632000

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

Jordan, Lebanon:
Hotline: +961 70122946
Email: PV.MEA@abbvie.com

How supplied

OPTIVE FUSION™ MD is supplied in a plastic bottle containing 10mL or 3mL and each carton contains a bottle of the product and an insert with instructions for use.

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

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

EC REP
ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED
Clonshaugh Business & Technology Park,
Dublin 17,
D17 E 400,
Ireland

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

CE 0344

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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***	***Combination of aseptic sterilization symbol with Single sterile barrier system***
Importer	***Intended for use multiple times on a single patient***	***Contains hazardous substances***	STERILE A ***Aseptic Sterilization***
Manufacturer's IFU website	MD ***Medical Device***	LOT ***Lot number***	***Expiry date (YYYY-MM-DD or YYYY-MM)***
REF 10077X	***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)***

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