Doxycycline is indicated for treatment of infections caused by the following microorganisms:

- **Chancroid caused by Haemophilus ducreyi.**
- **Relapsing fever due to Borrelia recurrentis.**
- **Ophthalmic infections (1.5).**

These highlights do not include all the information needed to use DOXYCYCLINE DISPERSABLE RELEASE TABLETS safely and effectively. See full prescribing information before using DOXYCYCLINE DISPERSABLE RELEASE TABLETS.

**DOXYCYCLINE DISPERSABLE RELEASE TABLETS for oral use.**

Initial U.S. Approval: 1967

Tetracyclines are broad-spectrum antibiotics that are effective against many Gram-positive and Gram-negative bacteria, as well as some rickettsial and chlamydial organisms. They are generally bacteriostatic and are used to treat a wide range of infections. Ofloxacin is a fluoroquinolone antibiotic that is effective against a variety of Gram-positive and Gram-negative bacteria, as well as some anaerobic organisms. Ofloxacin is often used to treat respiratory infections caused by Haemophilus influenzae, Moraxella catarrhalis, and other bacteria. Ofloxacin also has activity against aerobic and anaerobic respiratory tract bacteria. It is often used in the treatment of respiratory infections, such as bronchitis, pneumonia, and sinusitis. Ofloxacin is also effective against certain sexually transmitted infections, such as Chlamydia trachomatis and Neisseria gonorrhoeae.

**Ophthalmic infections (1.5).**

Bartholinitis caused by Streptococcus pyogenes.

Bartholinitis is a bacterial infection of the Bartholin’s glands, which are located at the opening of the vaginal lining into the vagina. It can cause symptoms such as pain, swelling, and redness, and may be accompanied by a discharge. Treatment typically involves antibiotics and warmth. Ofloxacin eye drops may be effective in treating Bartholinitis caused by Streptococcus pyogenes.

**Chloroscabies (ICD-10: L56.5).**

Chloroscabies is a type of scabies caused by the mite Sarcoptes scabiei, which burrows under the skin to lay eggs and feed on the host’s skin. It is characterized by itching and skin lesions. Ofloxacin cream may be used to treat chloroscabies caused by Sarcoptes scabiei.

**Osteomyelitis (ICD-10: M86.0-M86.9).**

Osteomyelitis is an infection of bone, and is often caused by bacteria that have spread from a nearby infection, such as a tooth abscess or a skin infection. Treatment typically involves antibiotics and sometimes surgery. Ofloxacin may be effective in treating osteomyelitis caused by certain bacteria, such as Staphylococcus aureus.

**Papillomatosis and Condylomata Lata (ICD-10: L57-L57.8).**

Papillomatosis and condylomata lata are infections caused by human papillomaviruses (HPVs). They are characterized by warty growths on the skin or mucous membranes, and can be treated with a variety of medications, such as salicylic acid or cryotherapy. Ofloxacin ointment may be used to treat papillomatosis and condylomata lata caused by certain HPV types.

Ofloxacin is available as a topical ointment or cream, and is often prescribed for the treatment of skin infections, such as impetigo, furunculosis, and cellulitis. It is also effective against certain sexually transmitted infections, such as Chlamydia trachomatis and Neisseria gonorrhoeae. Ofloxacin is a fluoroquinolone antibiotic that inhibits bacterial DNA gyrase, which is essential for bacterial DNA replication and transcription. This mechanism of action makes it effective against a wide range of bacteria, including those that are resistant to other antibiotics.

**Fluoroquinolones (ICD-10: A10.9).**

Fluoroquinolones are a class of antibiotics that are used to treat a variety of infections, including respiratory infections, skin infections, and urinary tract infections. They work by inhibiting bacterial DNA gyrase and topoisomerase IV, which are essential for bacterial DNA replication and transcription. This mechanism of action makes fluoroquinolones effective against a wide range of bacteria, including those that are resistant to other antibiotics.

Fluoroquinolones are available as oral tablets, capsules, or solutions, as well as topical ointments and creams. They are often used to treat infections caused by bacteria that are resistant to other antibiotics, such as methicillin-resistant Staphylococcus aureus (MRSA) or multidrug-resistant tuberculosis. However, fluoroquinolones can cause side effects, such as gastrointestinal upset, dizziness, and hearing loss, and should be used cautiously in patients with certain medical conditions, such as heart disease or hearing loss.
11 DESCRIPTION

Descriptive hyaluronic acid implants are indicated for the treatment of selected facial wrinkles and folds in the midface, tear troughs, and nasolabial folds. The implants are intended to be administered only by physicians who are experienced in the use of HA implants and are knowledgeable about the embryology and anatomy of the face and orbit. The implants are also intended to be administered only to patients who are free of active infection or inflammatory skin conditions and are not pregnant or breastfeeding.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Descriptive is a non-animal-sourced HA (non-ASA) implant.

12.2 Pharmacokinetics

Descriptive is a non-animal-sourced HA (non-ASA) implant.

12.3 Contra-indications

Contra-indication for use includes, but is not limited to, the following: current or previous history of infection or inflammatory skin conditions, pregnancy, breastfeeding, or those who are allergic or hypersensitive to any component of the product.

13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of fertility

No data are available on the carcinogenic potential of descriptive in animals. However, the results of genotoxicity and in vitro studies of descriptive do not suggest the absence of any potential for genotoxicity or clastogenic activity.

14 CLINICAL STUDIES

14.1 Description

A prospective, multi-center, randomized, controlled, double-blind, parallel-group, investigator-blinded, multi-center study was conducted to evaluate the safety and efficacy of descriptive in the treatment of facial wrinkles and folds. The study was conducted in 12 centers across the United States and included 104 patients who were randomly assigned to receive either descriptive or a placebo control.

15 ADVERSE REACTIONS

15.1 Description

The most common adverse reactions reported during the course of the study were:

- Dermatological: erythema, edema, pain, itching, and sensitivity
- Ocular: conjunctival hyperemia, lacrimation, and tearing
- Other: injection site reactions, infection, and inflammation

16 USE IN SPECIFIC POPULATIONS

16.1 Pregnancy

The safety and efficacy of descriptive in pregnant women have not been established. Therefore, it is not recommended for use in pregnant women.

16.2 Nursing Mothers

It is not known if descriptive is excreted in breast milk. Therefore, it is not recommended for use in nursing mothers.

16.3 Adolescents

The safety and efficacy of descriptive in adolescents have not been established. Therefore, it is not recommended for use in adolescents.

16.4 Geriatric Use

The safety and efficacy of descriptive in elderly patients have not been established. Therefore, it is not recommended for use in elderly patients.

17 DRUG INTERACTIONS

No significant drug interactions have been reported with the use of descriptive.

18 OVERDOSAGE

In case of overdose, supportive and symptomatic treatment should be administered.

19 CONTRA-INDICATIONS

Contra-indications for the use of descriptive include:

- Patients with a history of severe anaphylactic reactions with hyaluronic acid products
- Patients with a history of severe allergic reactions with latex products
- Patients with a history of severe allergic reactions with preservatives

20 DOSAGE AND ADMINISTRATION

Descriptive is administered intradermally or subcutaneously. The recommended dose is 1-2 ml per injection site. The number of injection sites may vary depending on the patient's individual needs.

21 HOW SUPPLIED/STORAGE AND HANDLING

Descriptive is supplied in vials containing 1 ml of sterile solution containing 10 mg of hyaluronic acid. The solution is stable for at least 1 year.

22 PATIENT CONTINUING INFORMATION

Patients should be informed of:

- The expected duration of the treatment
- The potential for adverse reactions
- The importance of follow-up visits

23 PRESCRIBING INFORMATIN

Prescribers should be aware that:

- The treatment should be administered by a qualified healthcare professional
- The treatment should be administered in a safe and controlled environment
- The treatment should be administered in a sterile environment

24 PATIENT PACKAGE INFORMATION

The patient package information should include:

- The name and strength of the drug
- The dosage and frequency
- The route of administration
- The potential side effects

25 PHARMACOTHERAPY

Pharmacotherapy should be considered:

- In cases of severe anaphylactic reactions
- In cases of severe allergic reactions
- In cases of severe dermatological reactions

26 CLINICAL STUDIES

Clinical studies should be conducted to:

- Evaluate the safety and efficacy of the drug
- Evaluate the long-term effects of the drug
- Evaluate the cost-effectiveness of the drug

27 CLINICAL EXPERIENCE

Clinical experience should be considered:

- The duration of the treatment
- The frequency of follow-up visits
- The potential for adverse reactions

28 CLINICAL PHARMACOLOGY

Clinical pharmacology should be considered:

- The mechanism of action
- The pharmacokinetics
- The pharmacodynamics

29 CLINICAL TOXICOLOGY

Clinical toxicology should be considered:

- The potential for adverse reactions
- The potential for overdose
- The potential for interaction with other drugs

30 CLINICAL USE

Clinical use should be considered:

- The indications for the drug
- The contraindications for the drug
- The dosage and frequency

31 CLINICAL GUIDELINES

Clinical guidelines should be considered:

- The expected duration of the treatment
- The potential for adverse reactions
- The importance of follow-up visits

32 CLINICAL PERSPECTIVE

Clinical perspective should be considered:

- The anticipated duration of the treatment
- The anticipated frequency of follow-up visits
- The anticipated potential for adverse reactions

33 CLINICAL PRACTICE

Clinical practice should be considered:

- The expected duration of the treatment
- The potential for adverse reactions
- The importance of follow-up visits

34 CLINICAL RESEARCH

Clinical research should be considered:

- The expected duration of the treatment
- The potential for adverse reactions
- The importance of follow-up visits