JUVÉDERM® XC Professional Full Fair Balance:

JUVÉDERM® XC Important Information

Indication

JUVÉDERM® XC injectable gel is indicated for injection into the mid-to-deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
JUVÉDERM® XC injectable gel should not be used in patients who have severe allergies, marked by a history of anaphylaxis or history or presence of multiple severe allergies, and should not be used in patients with a history of allergies to gram-positive bacterial proteins or lidocaine.

WARNINGS
- JUVÉDERM® XC injectable gel must not be injected into blood vessels and should not be used in vascular-rich areas. Use in these areas, such as glabella and nose, has resulted in cases of vascular embolization, occlusion of the vessels, ischemia or infarction, or blindness. Symptoms of vessel occlusion and embolization include pain that is disproportionate to the procedure or remote to the injection site, immediate blanching extending beyond the injected area, and color changes that reflect ischemic tissue such as a dusky or reticular appearance
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled

PRECAUTIONS
- The safety and effectiveness for the treatment of anatomic regions other than facial wrinkles and folds (such as lips) have not been established
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection. Follow standard precautions associated with injectable materials
- The safety for use during pregnancy and in breastfeeding females has not been established
- The safety for use in patients under 18 years has not been established
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied
- JUVÉDERM® XC injectable gel should be used with caution in patients on immunosuppressive therapy
- Patients who are using products that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may experience increased bruising or bleeding at treatment sites
- Patients should be limited to 20 mL of JUVÉDERM® XC per 60 kg (130 lbs) body mass per year. The safety of injecting greater amounts has not been established

ADVERSE EVENTS
The most commonly reported side effects are temporary injection-site redness, swelling, pain/tenderness, firmness, lumps/bumps, bruising, discoloration, and itching. Most side effects are mild or moderate in nature, lasting 7 days or less.

To report a problem with JUVÉDERM® XC, please call Allergan Product Surveillance at 1-800-624-4261.

For more information, please see the About Safety page at www.juvederm.com or call the Allergan Medical Information line at 1-800-433-8871.

JUVÉDERM® XC injectable gel is available by prescription only.