

NOW TREAT CROW'S FEET AND GLABELLAR LINES
SIMULTANEOUSLY
ONLY WITH VISTABEL®¹



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VISTABEL®, 4 Allergan-enheter/0,1 ml, pulver till injektionsvätska, lösning, Botulinumtoxin typ A, EF, Rx., ATC: M03AX01.

Indikationer: När följande ansiktsrynkor har en betydande psykologisk påverkan på vuxna patienter används VISTABEL för tillfällig förbättring av måttliga till uttalade: -vertikala rynkor mellan ögonbrynen som uppkommer vid maximal rynkning av pannan (glabellaveck); -rynkor i ögats utkanter som uppkommer vid maximalt leende (kråksparkar/skrattrynkor); -kråksparkar som uppkommer vid maximalt leende och glabellaveck som uppkommer vid maximal rynkning av pannan när dessa behandlas samtidigt. **Kontraindicerad:** Vid känd överkänslighet mot botulinumtoxin typ A eller mot något hjälpämne, myasthenia gravis eller Eaton-Lamberts syndrom och infektion vid det planerade injektionsstället. **Interaktioner:** Teoretiskt kan effekten av botulinumtoxin potentieras av aminoglykosidantibiotika eller spektinomycin, eller andra läkemedel som interfererar med neuromuskulär överföring (t.ex. neuromuskulärt blockerande medel). Effekten av samtidig administrering, eller administrering inom flera månader efter varandra, av olika serotyper botulinumneurotoxin är okänd. Överdriven neuromuskulär svaghet kan förvärras genom administrering av ett annat botulinumtoxin innan effekten av den tidigare dosen botulinumtoxin avklingat. Inga särskilda tester har utförts för att ta reda på om preparatet kliniskt interagerar med andra läkemedel. Inga andra interaktioner av klinisk betydelse har rapporterats för denna indikation. För ytterligare information om produkten se www.fass.se. Datum för senast godkänd produktresumé 2013-11-14.

References: 1. Vistabel SPC [Summary of Product Characteristics], 2013. 2. Internal Summary of Clinical Data Page 1 (Module 2.7.3 Clinical Efficacy Summary Figure 2.7.3-1) 3. Internal Summary of Clinical Data Page 6 (TABLE 3-27.2, MODULE 5.3.5.3 ISE TABLE 3-27.2).

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DOSING AND ADMINISTRATION GUIDE

Diagrammatic representation for illustrative purposes only. Please refer to SPC.

ONLY WITH
VISTABEL®

TREAT CROW’S FEET LINES (CFL) AND GLABELLAR LINES (GL) SIMULTANEOUSLY

Simple steps for dosing and administration of VISTABEL®

1. RECONSTITUTION

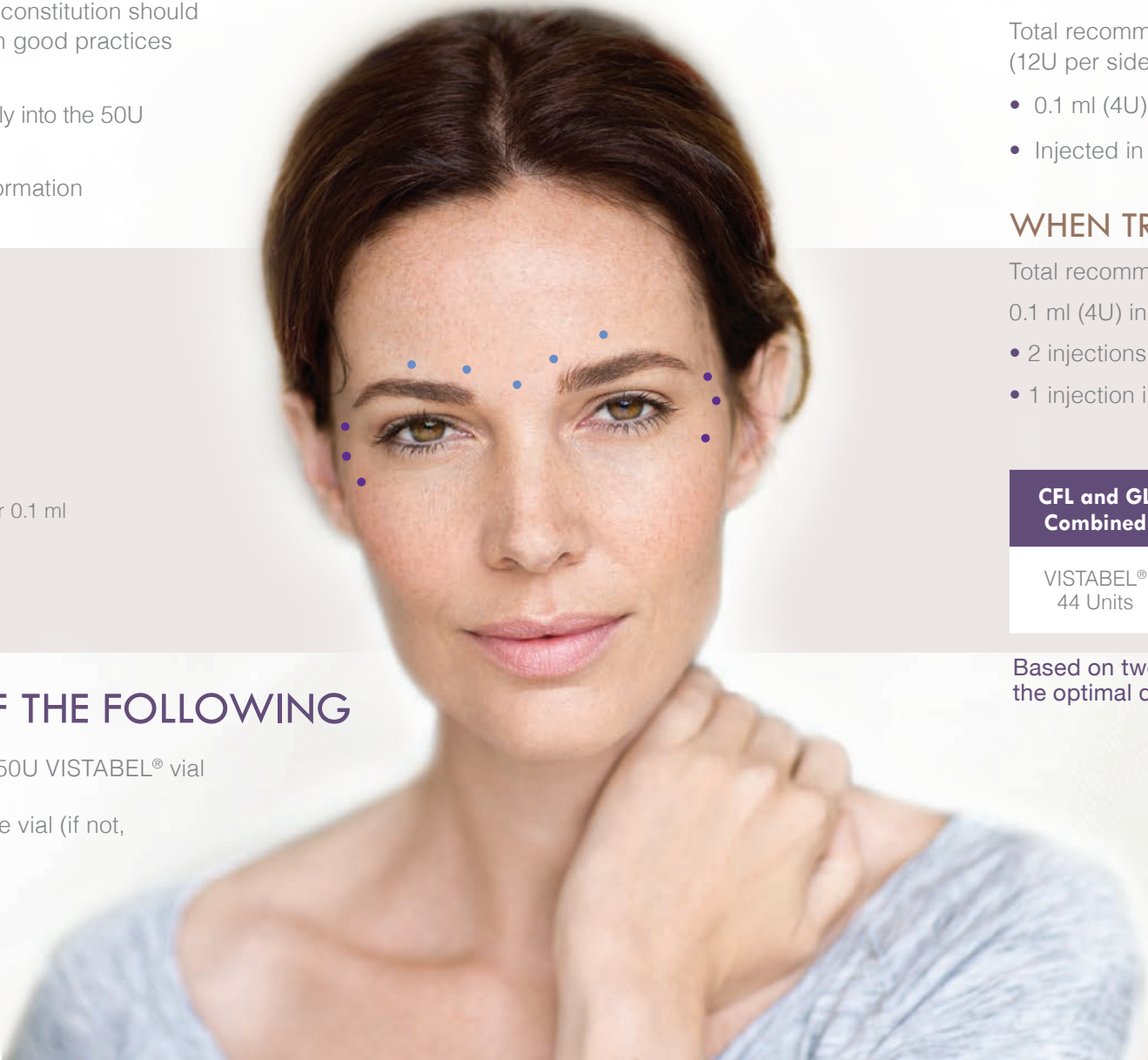
VISTABEL® is reconstituted with a 0.9% preservative-free sodium chloride solution. Reconstitution should be performed in accordance with good practices and aseptic technique¹.

- Inject 1.25 ml of the solvent slowly into the 50U VISTABEL® vial
- Gently rotate to avoid bubble formation and denaturation



MAKE CERTAIN OF THE FOLLOWING

- ✓ 1.25 ml of solvent added to 50U VISTABEL® vial
- ✓ Vacuum pulled solvent into the vial (if not, discard the vial)
- ✓ Solution is clear, colourless to slightly yellow, and without particles



2. DOSING

WHEN TREATING CFL

Total recommended dose: 24U in 0.6 ml (12U per side)¹

- 0.1 ml (4U) in each of 6 injection sites
- Injected in the lateral orbicularis oculi muscle

WHEN TREATING GL

Total recommended dose: 20U in 0.5 ml¹

0.1 ml (4U) in each of 5 injection sites:

- 2 injections in each corrugator muscle
- 1 injection in the procerus muscle

CFL and GL Combined		CFL		GL
VISTABEL® 44 Units	=	VISTABEL® 24 Units	+	VISTABEL® 20 Units

Based on two phase 2 dose-ranging studies, the optimal dose for CFL is 24U.²

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3. INJECTION

WHEN TREATING CFL¹

Injections should be given with the needle tip bevel up and oriented away from the eye.¹

The first injection (**A**) should be made approximately 1.5 to 2.0 cm temporal to the lateral canthus and just temporal to the orbital rim.

- If the lines in the crow’s feet region are above and below the lateral canthus, inject as shown in Figure 1
- If the lines in the crow’s feet region are primarily below the lateral canthus, inject as shown in Figure 2

Figure 1

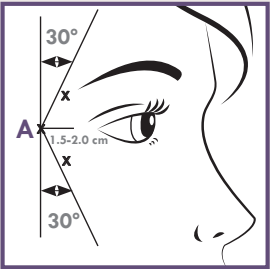
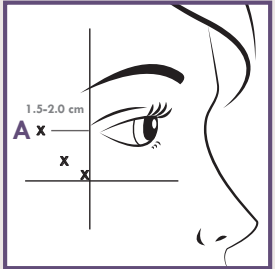


Figure 2



WHEN TREATING GL¹

- Before injection, place the thumb or index finger firmly below the orbital rim to prevent extravasation below the orbital rim
- Orient the needle superiorly and medially during injection

Injections near the levator palpebrae superioris muscle must be avoided to reduce the risk of ptosis, particularly in patients with larger brow-depressor complexes (depressor supercilii).

Injections in the corrugator muscle must be done in the central part of that muscle, at least 1 cm above the arch of the eyebrows.

INDICATION

When the severity of the following facial lines has an important psychological impact in adult patients, VISTABEL® is indicated for the temporary improvement in the appearance of:

- Moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines)
- Moderate to severe lateral canthal lines (crow’s feet lines) seen at maximum smile
- Moderate to severe crow’s feet lines seen at maximum smile and glabellar lines seen at maximum frown when treated simultaneously

SOME REASONABLE EXPECTATIONS

- Patients treated for CFL and GL simultaneously may see greater improvements than with CFL alone³
- Patients may see improvement within 2-3 days of injection¹
- Results may last up to 4 months¹
- Interval between treatments must not be less than 3 months