



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by
Actegy Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, on receipt of an application from Actegy Pty Ltd have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraph **(A)**, (which must be accompanied by the advisory statements set out in paragraph **(B)**) and the restricted representation in paragraph **(C)** for use in advertisements directed to consumers for the products identified in paragraph **(D)**:

(A)

- Revitive may reduce leg pains when walking caused by poor circulation associated with medically diagnosed peripheral arterial disease.
- Revitive may improve circulation in the legs during use, caused by poor circulation associated with medically diagnosed peripheral arterial disease.
- Revitive may improve circulation to reduce or prevent blood-pooling (stasis) during use, caused by mild varicose veins.
- Revitive may increase walking distance before the onset of claudication symptoms (pain) caused by poor circulation associated with medically diagnosed peripheral arterial disease.
- Inactivity, a sedentary lifestyle, smoking, living with diabetes, high blood pressure or high cholesterol are risk factors for poor circulation associated with peripheral arterial disease. Consult your doctor.

(B)

- Warning: Consult your health care professional before use.
- Do not use if:
 - fitted with an electronic implanted device such as a heart pacemaker or AICD;
 - pregnant; or
 - being treated for, or have symptoms of a DVT, such as pain, swelling and tenderness, heavy ache, warm or red skin in the leg.
- Revitive is not designed to replace your existing treatment plan (or words to this effect).

(C)

IFU warning: Leg symptoms, especially where combined with certain underlying medical conditions, such as high blood pressure, high cholesterol, smoking or diabetes may be an indicator of poor circulation associated with peripheral arterial disease.

(D)

Products marketed as “Revitive” under the following entries in the Australian Register of Therapeutic Goods (ARTG):

- Actegy Pty Ltd – Stimulator, electrical, analgesic, peripheral nerve, transcutaneous (ARTG 206176)
- Actegy Pty Ltd – Analgesic TENS system (ARTG 283529)

Dated this 19th Day of March 2021

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch