

Ministry of Health

DIRECTORATE GENERAL OF PREVENTIVE HEALTH CARE OFFICE IV

Viale Giorgio Ribotta, 4- 00144 Rome

To the Company
Ferrarelle S.p.A.
Via di Porta Pinciana, 4
00187 Rome

Classification: I.5.h.h.

SUBJ.: Director's Decree No. 4161 of 8 January 2015. Natural mineral water "Antica Fonte" in the Municipality of Darfo Boario Terme (Brescia). Indications for use.

Hereto attached is the true copy of the director's decree referred to in the subject line.

Head of Procedure
(Dr Elda Di Natale)

THE HEAD OF OFFICE
(Dr Liliana La Sala)

Ministry of Health

DIRECTORATE GENERAL OF PREVENTIVE HEALTH CARE OFFICE IV

DECREE DATED 8 JANUARY 2015

Natural mineral water "Antica Fonte" in the Municipality of Darfo Boario Terme (Brescia) - Indications for use.

THE DIRECTOR GENERAL

HAVING REGARD to the application filed on 13 October 2014 by which the company Ferrarelle S.p.A., with registered office in Rome, Via Di Porta Pinciana 4, requested to place the indications for use on the labels of the natural mineral water Antica Fonte di Darfo Boario Terme (Brescia):

HAVING EXAMINED the submitted documents;

HAVING REGARD to Italian Ministerial Decree No. 38 of 20 April 1925 authorising the sale of the mineral water Antica Fonte;

HAVING REGARD to the Director's Decrees No. 3048-036 of 16 June 1998 and No. 3239-036 of 30 December 1999 confirming the recognition of said mineral water and authorising the labels with the following wording: May have diuretic effects; may have laxative effects and a favourable action on hepatobiliary functions;

HAVING REGARD to Italian Legislative Decree No. 176 of 8 October 2011 implementing Directive 2009/54/EC on the exploitation and marketing of natural mineral waters;

HAVING REGARD to Italian Ministerial Decree No. 542 of 12 November 1992, as amended by the Italian Ministerial Decree of 29 December 2003;

HAVING REGARD to the Italian Health - Production Activities Interministerial Decree of 11 September 2003;

HAVING REGARD to the opinion of Section III of the Italian High Council on Health expressed at the meeting on 16 December 2014;

HAVING REGARD to Italian Legislative Decree No. 165 of 30 March 2001;

HEREBY DECREES:

Article 1

1) The labels of the natural mineral water Antica Fonte di Darfo Boario Terme (Brescia), pursuant to article 12(4)(h) of Italian Legislative Decree No. 176 of 8 October 2011 may bear, in addition to the wordings already authorised, the following indication for use: **"We recommend drinking two glasses (about 400 mL) every day, at room temperature, preferably in the morning, on an empty stomach, before breakfast for the product to have a good degree of efficacy."**

This Decree shall be published in the Official Journal of the Italian Republic.

A copy of this decree will be forwarded to the applicant and to the competent regional bodies.

Rome, 8 January 2015

THE DIRECTOR GENERAL
(Dr Raniero Guerra)