



## Warnings on Actavis Products

In case of suspected adverse reactions following intake of an Actavis drug, please, contact your general practitioner or go to an Emergency Room immediately.

The general practitioner, the pediatrician and the pharmacist must send the report of suspected adverse reaction to the ASL of competence.

The hospital doctor and the hospital pharmacist must submit the report to the Health Department of the Hospital.

The Pharmacovigilance Service Hospital or Health Authority will insert the report in the network of Pharmacovigilance

Should you need contact Pharmacovigilance Department of Actavis Italy SpA, please use the following contacts:

Tel +39 0331 583204 - 583169

Fax no +39 0331 583450

E-mail: [RegulatoryAffairsIT@actavis.com](mailto:RegulatoryAffairsIT@actavis.com)

In case of other warnings relevant to defects identified on Actavis products, please, forward your complaint to the following e-mail addresses:

- [Nervianocomplaints@actavis.com](mailto:Nervianocomplaints@actavis.com)

And make sure to include the following information:

- Product name (see example bottom of page)
- API name (see example bottom of page)
- Batch number (see example bottom of page)
- Description of the defect (description of the complaint / warning)
- Sample availability: please, keep the sample object of the complaint to allow manufacturing site to carry out relevant investigations. We recommend sticking to the storage conditions indicated either on the box or in the leaflet of the product itself.

Name of the person making the complaint

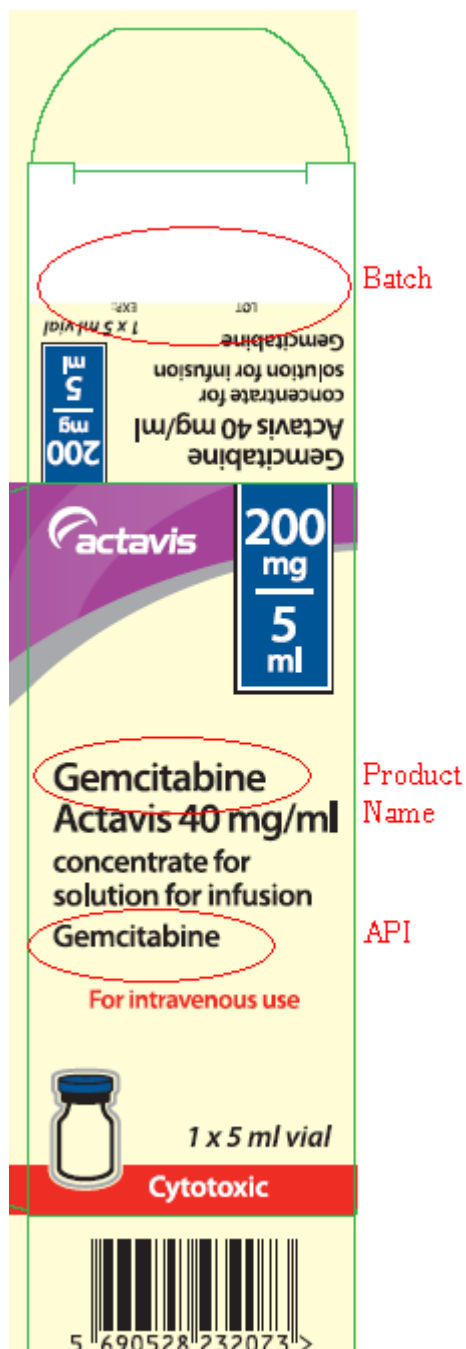
- Relevant contact details (address and/or e-mail address and/or phone number). In case this information is missing, complaint will not be taken into consideration.

In case of extremely urgent warnings, please contact any of the following phone numbers:

- Monday thru Friday, from 08.30 to 17.30 :  
+39 0331 583205  
+39 0331 583149  
+39 0331 583447

During other days/hours, festivities and company closure days please contact the following mobile: +39 340 0913846

Information to be supplied:



Privacy:

Legislative Decree n. 196, dated June, 30<sup>th</sup> 2003, called “Code relevant to the handling of personal data” (hereinafter referred to as the Code), replaced Law 675/96. It guarantees that personal data handling is carried out respecting fundamental rights, freedom and dignity of the interested subject, with particular attention to secrecy, personal identity and personal data protection. Given the above, Actavis Italy SpA, with registered offices in Via Pasteur, 10 – 20014 – Nerviano (MI), as a “Holder”, is called to supply you with precise information, as per art. 13 of the Code, on the handling of your personal data:

## 1. SCOPE OF DATA HANDLING

Personal data object of the handling will be used for the following reasons only:

- compliance with laws and regulations coming from duly legitimized Authorities
- creation and management of the assistance and service program.

These personal data will of course be managed in full compliance with Privacy Law.

In order to fulfill above mentioned items and to correctly manage your warning, personal data indication is mandatory. In case personal data are not indicated, the warning itself shall not be taken into consideration.

## 2. HANDLING PROCEDURES

Personal data handling requires gathering, registration, storage and modifications of the data themselves by means of manual, IT and telematic instruments. Rationale for the handling is strictly related to the data handling scope and is carried out in order to guarantee safety and secrecy of the data themselves.

Data will not be either communicated or shared. Moreover, they shall be handled with the co-operation of third parties, openly appointed as Responsible or In Charge of the Handling.

## 4. RIGHTS COVERED BY ART. 7

We also hereby communicate that, as provided for by the Code:

- **Holder** of the handling is ACTAVIS ITALY S.P.A., with registered offices in Viale Pasteur, 10 - 20014 Nerviano (MI), in the person of the Managing Director, pro tempore legal representative, Eng. Davide Improta
- **Responsible** of the handling is the pro-tempore responsible of the QO dept., resident for this position at ACTAVIS ITALY S.P.A., with registered offices in Viale Pasteur, 10 - 20014 Nerviano (MI).

It is possible to check use of the data, correct and/or update them or refuse their handling, as provided for by art. 7 of the Code, by contacting the above mentioned Responsible.

Updated list of the Handling responsible is available at ACTAVIS ITALY S.P.A., Viale Pasteur 10, 20014 Nerviano (Milano).

ACTAVIS ITALY S.P.A.