

Adverse Drug Reaction Reporting as you work and straight from eMIMS

You will find the TGA's adverse drug reaction form in the **Abbreviated Prescribing Information** for all prescription, over the counter and herbal medicines in eMIMS. Simply choose the medicine you want to look at, from the pick list on the left of your screen and when it displays the first content you see is the **Abbreviated Prescribing Information (API)**

The screenshot shows the eMIMS software interface for August 2012. The main window displays the product page for 'Aci-Jel'. The 'MIMS Abbreviated Prescribing Information' section is highlighted with a red circle and a red arrow pointing to it from the text above. The interface includes a search bar, a list of products on the left, and detailed product information on the right.

Aci-Jel
MIMS Abbreviated Prescribing Information
multiple actives.
Care Pharmaceuticals
Section: 7(d) Topical vaginal medication - Genitourinary System
Use in pregnancy
Permitted in sport
Use: Buffer. Vaginal acidity restoration and maintenance
Precautions: Pregnancy, lactation
Adverse Reactions: TGA Report Form Local irritation, inflammation (rare)

Aci-Jel (Gel) (Unscheduled)
Ricinoleic acid 0.70%, acetic acid 0.94%, hydroxyquinoline sulfate 0.025%, glycerol 5%; propyl hydroxybenzoate; pale yellow, perfumed acetic acid odour
Dose: 1 applicatorful (5 g) intravaginally morning and night
Pack 100 g [1] - RPBS or \$28.52
PBS: \$33.00

MIMS Full Prescribing Information
MIMS revision date: 1/08/2008
Name of the medicine Acetic acid 0.94%, hydroxyquinoline sulfate 0.025%, ricinoleic acid 0.7%, glycerol 5%.
Excipients. Tragacanth, acacia, propyl hydroxybenzoate, potassium hydroxide, stannous chloride, albumin, potassium acid tartrate, perfume, water; pH 4.
Actions Aci-Jel Therapeutic: Vaginal Jelly acts to restore and maintain normal vaginal acidity through its buffer action.
Indications Restoration and maintenance of vaginal acidity.
Contraindications Sensitivity to any component.
Precautions General. Although the concentration of the preservative, propyl hydroxybenzoate (0.05%), in Aci-Jel is well below the usual concentration causing allergic reactions in sensitive individuals, the doctor should be alert to the possibility of a sensitivity reaction. If encountered, discontinue use and flush vulvovaginal tissues with water.
Laboratory tests. The monitoring of vaginal acidity (pH) may be helpful in following the patient's response. (The normal vaginal pH has been shown to be in the range of 4 to 5.)
Carcinogenesis, mutagenesis, impairment of fertility. Carcinogenesis. No long-term studies in animals have been performed to evaluate carcinogenic potential.
Use in pregnancy. Animal reproduction studies have not been conducted with Aci-Jel. It is not known whether Aci-Jel can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Although there is no evidence that any of the components of this product are detrimental to the mother or fetus, the use of any drug during pregnancy should be carefully assessed, and administered only if clearly indicated.

If you are looking at the Abbreviated PI you will find see the words **TGA Report Form** next to the **Adverse Reactions**.

The screenshot displays the eMIMS MIMS, August 2012 interface. The main content area is titled "Aci-Jel" and contains the following information:

- MIMS Abbreviated Prescribing Information**
 - multiple actives
 - Care Pharmaceuticals
 - Section: 7(d) Topical vaginal medication - Genitourinary System
 - Use in pregnancy: Permitted in sport
 - Use: Buffer, Vaginal acidity restoration and maintenance
 - Precautions: Pregnancy, lactation
 - Adverse Reactions: **TGA Report Form** Local irritation, inflammation (rare)
- Aci-Jel (Gel) (Unscheduled)**
 - Ricinoleic acid 0.70%, acetic acid 0.94%, hydroxyquinoline sulfate 0.025%, glycerol 5%; propyl hydroxybenzoate; pale yellow, perfumed acetic acid odour
 - Dose: 1 applicatorful (5 g) intravaginally morning and night
 - Pack 100 g [1] : RPBS or \$28.52
 - PBS: \$33.00
- MIMS Full Prescribing Information**
 - MIMS revision date: 1/08/2008
 - Name of the medicine: Acetic acid 0.94%, hydroxyquinoline sulfate 0.025%, ricinoleic acid 0.7%, glycerol 5%
 - Excipients: Tragacanth, acacia, propyl hydroxybenzoate, potassium hydroxide, stannous chloride, albumin, potassium acid tartrate, perfume, water, pH 4
 - Actions: Aci-Jel Therapeutic Vaginal Jelly acts to restore and maintain normal vaginal acidity through its buffer action.
 - Indications: Restoration and maintenance of vaginal acidity.
 - Contraindications: Sensitivity to any component.
 - Precautions General: Although the concentration of the preservative, propyl hydroxybenzoate (0.05%), in Aci-Jel is well below the usual concentration causing allergic reactions in sensitive individuals, the doctor should be alert to the possibility of a sensitivity reaction. If encountered, discontinue use and flush vulvovaginal tissues with water.
 - Laboratory tests: The monitoring of vaginal acidity (pH) may be helpful in following the patient's response. (The normal vaginal pH has been shown to be in the range of 4 to 5.)
 - Carcinogenesis, mutagenesis, impairment of fertility, Carcinogenesis: No long-term studies in animals have been performed to evaluate carcinogenic potential.
 - Use in pregnancy: Animal reproduction studies have not been conducted with Aci-Jel. It is not known whether Aci-Jel can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Although there is no evidence that any of the components of this product are detrimental to the mother or fetus, the use of any drug during pregnancy should be carefully assessed, and administered only if clearly indicated.

If you are in an abbreviated PI for an herbal or OTC medicine there may not be any **Adverse Reactions** in the Abbreviated PI. In this case you will find the **TGA Report Form** in the content.

The screenshot shows the eMIMS MIMS August 2012 interface. The main content area displays the following information for 'Acne Gel with Sanchi':

- MIMS Abbreviated Prescribing Information:** nicotinamide; panax notoginseng root powder
- Nutriherbs**
- Section: 22(h) Herbal skin preparations - Herbal and other complementary medicines**
- TGA Report Form** (highlighted with a red circle)
- As herbal products may contain unspecified ingredients, they cannot be guaranteed as permitted in sport.**
- Use:** Assist with topical treatment of acne; reduce assoc. inflammation, soothe irritation; may improve peripheral circulation
- Acne Gel with Sanchi (Unscheduled)**
- Ingredients:** Panax notoginseng (Sanchi) root extract 90 mg/g; vit B₃ 40 mg/g; ethanol; gluten free
- Dose:** Wash face. Apply gel to affected area, massaging into skin. Repeat 2-3 times daily
- Pack 25 g [1] : \$10.90**
- For further information Contact Manufacturer**
- Please refer to disclaimer**
- Jump To Top**

To access the form:

Because some of you have told us you do not always have internet access on the computer you load eMIMS on to when working, we have provided two ways of accessing, completing and sending the TGA Report Form.

1. With Internet Access

If your computer is connected to the internet, simply click on the blue hyperlink. [TGA Report Form](#), which will take you to the screen below. **Click yes** to proceed and you will go directly to the form below.

Adverse Drug Reaction Form

In this system, you can report a case of a suspected adverse reaction in association with a medicine (including complementary, OTC or prescription) or a vaccine.

Please note: The personal information in this form is collected and used for the purpose of assessing the safety of medicines under the Therapeutic Goods Act 1989. The personal information is only disclosed (i) to State or Territory Health Departments (if the information relates to Immunisation Schedule events); or (ii) where there is a legal requirement to disclose it. The reporter's details are recorded in the database so that reporters can be contacted if further information is required.

Do you wish to proceed?

All you have to do now is complete the details on your screen and email the form to the TGA directly from eMIMS – **there is an email button at the end of the form**

Adverse Drug Reaction Form

All dates must be entered in DD/MM/YYYY Format.
Fields marked * are mandatory.

Patient Details

ID or Initial * :

Gender * : Male Female Unknown

Date of Birth * : or Age : in Years
Please enter the Date of Birth in DDMMYYYY format.
If date of birth is not known please enter Age and Age Unit.
If the Age is unknown, enter 99u in the Age field.

Medicine Details (Minimum of one entry required) *

[Add Medicine Details](#) (Click to add Medicine Details)

DrugID	Drug	Dose	Frequency	Form	Route	Date	Start Date	Stop	Reason for Use	Batch No.	ARTG ID
Edit Delete	1	4.3.2.1	Energy	Recharge							

Reaction Details

Reaction Onset Date : (dd/mm/yyyy)

Adverse Reaction Description * :

Severity :

Treatment of Reaction :

Outcome : Unknown
If outcome is 'Death' or 'Recovered' enter Date of Outcome:

Sequelae of Reaction : No Yes

2. With NO Internet access

If your computer is not connected to the internet eMIMS will direct you to another version of the form (the blue form) that can be completed on your screen, printed and faxed to the TGA.

Report of suspected adverse reaction to medicines or vaccines - Adobe Reader

Please fill out the following form. You can save data typed into this form.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office use only

Report of suspected adverse reaction to medicines or vaccines
(See statement about the collection and use of personal information overleaf)
Please attach any additional data to this sheet

Patient initials or medical record number: _____ Sex: M F Date of birth or age: _____
Weight (kg): _____

Suspected medicine(s)/vaccine(s)
(please use trade names; include AUST R or AUST L number for non-prescription medicines, and batch number (if known))

Medicine/vaccine	Dosage (Dose number for vaccines eg 1- DTP)	Date begun	Date stopped	Reason for use

Other medicine(s)/vaccine(s) taken at the time of the reaction

Medicine/vaccine	Dosage	Date begun	Date stopped	Reason for use

Reaction(s): _____ Date of onset of reaction (or for vaccines time after administration): ____/____/____
Describe (please provide as much detail as possible and include any results of relevant supportive laboratory data and other investigations)

Seriousness: Life threatening Hospitalised Required a visit to doctor

Treatment of reaction: _____