Adverse Drug Reaction Reporting Form

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Grindex

Kalcex

Receive date

Follow up: ☐ Yes ☐ No

1*. PATIENT INFORMATION

Initials	Age	Sex	Age group
		☐ Male ☐ Unknown ☐ Female ☐ Other	☐ Neonate ☐ Child ☐ Adult ☐ Infant ☐ Adolescent ☐ Elderly

Additional relevant patient information (e.g., weight and height):

2*. REPORTER INFORMATION

Name, Surname	Phone No	Reporter's qualification
Country	E-mail	☐ Physician ☐ Other Health Care Professional *(Please specify)* ☐ Consumer or Non-Health Care Professional ☐ Pharmacist ☐ Unknown

Additional relevant reporter information (e.g. Organisation name, city/town):

3*. SUSPECT DRUG(S)

Brand name or Active substance	Indication for use	Dose, Units, Route Used	Frequency	Action taken with Suspect Drug
				☐ drug withdrawal ☐ dose increased ☐ unknown ☐ dose reduced ☐ dose not changed

Start Date | End Date | Lot No

Additional relevant suspect drug information (e.g.experation date):

4*. ADVERSE DRUG REACTION DESCRIPTION

Diagnosis of ADR(s). If diagnosis is not known, provide symptom(s)

Start date

End date or duration

Outcome
☐ Resolved ☐ Not resolved
☐ Resolved with sequelae ☐ Fatal
☐ Resolving ☐ Unknown

Is ADR serious? ☐ Yes ☐ No

If Yes, please, select criteria below
☐ Death(dd /mm /yyyy)
☐ Hospitalization / Extended Hospitalization
☐ Persistent or Significant Disability/ Incapacity
☐ Congenital Abnormality or Birth Defect
☐ Life-Threatening
☐ Other Significant Medical Event

Did ADR improve after stopping or reducing drug?
☐ Yes
☐ No
☐ Unknown

Did ADR reappear after reintroduction?
☐ Yes
☐ No
☐ Unknown

Additional drug reaction description description information (e.g. cause of death, autopsy results):

ADDITIONAL INFORMATION

Please provide relevant information on the ADR, relevant medical history and concurrent conditions, concomitant medications, performed investigations and results

* Required fields

The marketing authorization holder will take appropriate measures to ensure that given information is appropriately stored in accordance with Personal Data Protection Regulation. Before transfer of any personal information, patient name or any other information that would allow to identify patient will be replaced by a code.