**NEW ALLERGIC DRUG REACTION REPORTING FORM**

See instructions on how to use this form on reverse side.

<table>
<thead>
<tr>
<th>SUSPECTED DRUGS (List in order of probability)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug name</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
</tbody>
</table>

**Key Clinical Manifestations**

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Day</th>
<th>Started</th>
<th>Year</th>
<th>Month</th>
<th>Day</th>
<th>Ended</th>
<th>Ongoing</th>
</tr>
</thead>
</table>

Interval between dose and reaction (e.g., minutes/hours/days) ___________

**Cutaneous manifestations**

<table>
<thead>
<tr>
<th>(Check all that apply)</th>
<th>Other manifestations</th>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mucous membrane involvement</td>
<td>Gastrointestinal</td>
<td>(e.g., location of lesions, severity, etc.)</td>
</tr>
<tr>
<td>Bullae/pustules</td>
<td>Fever &gt; 38 °C</td>
<td></td>
</tr>
<tr>
<td>Desquamation</td>
<td>Hematologic</td>
<td></td>
</tr>
<tr>
<td>Maculopapular rash</td>
<td>Hepatic</td>
<td></td>
</tr>
<tr>
<td>Edema</td>
<td>Hypotension</td>
<td></td>
</tr>
<tr>
<td>Palpable purpura</td>
<td>Renal</td>
<td></td>
</tr>
<tr>
<td>Urticaria</td>
<td>Respiratory</td>
<td></td>
</tr>
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**Other manifestations**

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Manifestations disappeared after withdrawal of drug

Hospitalization required

If yes, please specify (e.g., emergency department, intensive care unit):

**Treatment for key clinical manifestations**

- [ ] None
- [ ] Systemic corticosteroid
- [ ] Epinephrine
- [ ] Antihistamine
- [ ] Topical corticosteroid
- [ ] Other:

Response to treatment: [ ] Yes [ ] No (Please specify):

**Current allergy status**

- [ ] Confirmed allergy: ___________
- [ ] Suspected allergy: ___________

**Referral for allergy consultation**

- [ ] Yes [ ] Date Year Month Day
- [ ] No Year Month Day

**Conclusions:** Please specify the severity of the observed allergic reaction (see details on reverse side)

- [ ] Immediate allergic reaction (IgE-mediated, or type I)
  Severity (Please specify):

- [ ] Delayed allergic reaction (type II, III or IV)
  Severity (Please specify):

- [ ] Not known

**Signature**

License No. ___________ Date Year Month Day
General instructions

Any health professional (e.g., physician, nurse or pharmacist) who suspects an allergic reaction may use this form. Do not use this form to report a predictable adverse drug reaction caused by a non-allergic intolerance or that is pseudoallergic in nature, or to report the allergy history provided by the user.
– Use only to report allergic reactions to drugs.
– Report all suspected allergic reactions that you observe.
– Sign and date the form at the bottom.

Suspected Drugs

– You can report up to three suspected drugs with each form (if applicable), starting with the most probable drug and providing the treatment start and end dates.

Key Clinical Manifestations

– Report only the clinical manifestations of allergic reactions that you cannot clearly link to one or more preexisting conditions, by checking all of the listed items that apply.
– Indicate the observed manifestations by checking one or more of the items listed and/or describe them in your own words in the space provided under “Additional Information”. Examples:
  • Type and location of edema (e.g., lips, tongue, throat, face or generalized);
  • Gastrointestinal problem (e.g., vomiting or severe diarrhea);
  • Hematologic disorder (e.g., adenopathy, anemia, eosinophilia or lymphocytosis);
  • Renal impairment (e.g., proteinuria or an increase in the urea and/or creatinine level);
  • Hepatic impairment (e.g., an increase in transaminase levels);
  • Respiratory impairment (e.g., breathing difficulties, bronchospasm, dyspnea, dysphonia or stridor).
– Indicate whether the observed clinical manifestations disappeared after withdrawal of the suspected drug or drugs, and if the user required hospitalization.

Additional information

– Indicate, if appropriate, any medical history that could potentially influence the reported clinical manifestations, such as prior known drug allergies, a concomitant HIV and other viral infection (e.g., Epstein-Barr virus) and/or concomitant diseases (e.g., cystic fibrosis or chronic urticaria).

Treatment for key clinical manifestations

– Indicate whether the reaction required treatment. If it did, indicate the treatment and the response to it.

Current allergy status

– Indicate whether the allergy has been confirmed by a physician by means of valid, appropriate tests (skin or provocation test) or by the occurrence of convincing clinical manifestations (e.g., anaphylactic shock, SJS/TEN or DRESS).
– Indicate whether a health professional suspects an allergy after having observed clinical manifestations suggestive of an allergic reaction but which require further investigation.

Referral for allergy consultation

– If more than one drug is suspected, it is highly recommended that user be referred to an allergy consultation.
– The consultation request should be accompanied by this duly completed form.
– Once the drug allergy has been confirmed by a physician with valid and appropriate tests, a new “Allergic Drug Reaction Reporting Form” should be duly completed in order to update the user’s medical record.

Conclusions and severity of the observed allergic reaction

– Indicate whether the observed reaction was immediate (IgE-mediated) and non-severe (e.g., isolated urticaria), severe (e.g., anaphylaxis without shock or intubation) or very severe (e.g., anaphylactic shock).
– Indicate whether the observed reaction was delayed and non-severe (e.g., isolated maculopapular eruption (rash)), severe (e.g., serum sickness, maculopapular eruption with desquamation, fever, joint pain or slight internal organ involvement) or very severe (e.g., hemolytic anemia, hepatic or renal involvement, SJS/TEN, DRESS or AGEP).

Once this form is completed

– Keep this form in the user’s medical record in accordance with the institution’s rules and, whenever possible, send a copy of the form to the other health professionals involved in the user’s care.
– Keep complete, up-to-date information on the user’s drug allergy status in his/her medical record and include this information in other documents, as specified in the institution’s rules.
– Take the necessary steps to clearly inform the user or legal guardian of the diagnosis, the type of reaction and the name of the drug (where appropriate) that caused it.