Online Purchasing of Isotretinoin: E-Pharmacies Provision of Safety Information

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BACKGROUND

Isotretinoin (brand name Accutane®/Roaccutane®) is a known teratogen. The purpose of Isotretinoin Pregnancy Prevention Programs (PPP) is to utilise a variety of approaches and strategies to control the prescription of, and diminish the risks of women of child bearing age receiving this medication during pregnancy. The prescribing of isotretinoin has been limited to dermatologists and selected clinicians¹,²; however, with the growing phenomenon of online pharmacies, consumers are now able to purchase Isotretinoin online³-⁴.

OBJECTIVES

A structured survey of e-pharmacies selling Isotretinoin to evaluate what safety measures and regulations are in place for women of child bearing age.

METHOD

The term ‘buy isotretinoin’ was entered into the five most commonly used search engines. Ten different online pharmacies URL’s (Uniform Resource Locator) from each search engine, all selling isotretinoin were stored for evaluation.

Two researchers (BML, BW) independently reviewed and evaluated the safety information content of each of the fifty sites for accuracy and completeness using PPP criteria derived from the US Food and Drug Administration (FDA)¹ and the UK Medicines and Healthcare Regulatory Agency (MHRA)² for dispensing Isotretinoin to women at risk of pregnancy.

RESULTS

The geographical location of the 50 e-pharmacies spanned over 10 countries. Only 7 (14%) of the sites could be categorised as a ‘legitimate’ online pharmacy (Fig 1.).

Table 1: Evaluation of information provided by e-pharmacies (n=50) on Isotretinoin and pregnancy using MHRA and FDA (iPLEDGE) PPP criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Fully Met</th>
<th>Partially Met</th>
<th>Not Met (legitimate site n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isotretinoin may be teratogenic/can cause severe birth defects</td>
<td>24</td>
<td>1</td>
<td>25</td>
</tr>
<tr>
<td>Speak to a doctor before taking</td>
<td>9</td>
<td>8</td>
<td>33</td>
</tr>
<tr>
<td>Do not take in pregnancy</td>
<td>20</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>Do not take if planning a pregnancy</td>
<td>14</td>
<td>3</td>
<td>33</td>
</tr>
<tr>
<td>Must have two negative pregnancy tests prior to starting therapy</td>
<td>6</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>Use two forms of contraception</td>
<td>18</td>
<td>1</td>
<td>31</td>
</tr>
<tr>
<td>Avoid progesterone only pill</td>
<td>3</td>
<td>13</td>
<td>34</td>
</tr>
<tr>
<td>Certain medicines may make contraceptives less effective e.g. St John’s Wort</td>
<td>2</td>
<td>2</td>
<td>46</td>
</tr>
<tr>
<td>Monthly pregnancy test</td>
<td>7</td>
<td>9</td>
<td>34</td>
</tr>
<tr>
<td>Do not get pregnant for at least one month after stopping treatment</td>
<td>16</td>
<td>1</td>
<td>33</td>
</tr>
<tr>
<td>Inform your doctor immediately if you become pregnant while taking</td>
<td>6</td>
<td>3</td>
<td>41</td>
</tr>
<tr>
<td>Increases chance of miscarriage</td>
<td>4</td>
<td>1</td>
<td>45</td>
</tr>
<tr>
<td>Do not share medicine with anyone else, particularly females</td>
<td>1</td>
<td>13</td>
<td>36</td>
</tr>
</tbody>
</table>

*One site provided a link to the FDA iPLEDGE program and therefore met all criteria.

CONCLUSIONS

Women of child bearing age have the option to self-purchase Isotretinoin directly from web sites that do not provide any form of risk assessment, pregnancy prevention education, or warnings of the dangers associated with taking this medication.

These findings have implications for the design of Pregnancy Prevention Programmes, for clinicians, and for the legal regulation of Internet pharmacies.

REFERENCES


ACKNOWLEDGEMENTS

• This study was part of the EUROMEDICAT research project (www.euromedicat.eu) which has been supported by the European Commission under the 7th Framework Programme Grant agreement n°: 260598
• Conflict of Interest: None

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