ADVERSE REACTIONS

In a large-scale clinical trial involving 100,000 women, the incidence of various adverse reactions was recorded. Table 1 summarizes the most common findings. As with any treatment, it is advisable to monitor the patient closely for signs of potential intolerance.

Table 1. Adverse Reactions and Incidence

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema nodosum</td>
<td>1.5%</td>
</tr>
<tr>
<td>Change in menstrual flow</td>
<td>0.3%</td>
</tr>
<tr>
<td>Porphyria</td>
<td>0.05%</td>
</tr>
<tr>
<td>Edema</td>
<td>20%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>34%</td>
</tr>
</tbody>
</table>

ADVERSE REACTIONS IN RISK GROUPS

Certain risk groups may experience adverse reactions more frequently or severe. Specific precautions should be taken for patients with pre-existing conditions, such as diabetes, hypertension, and cardiac disease.

INDICATIONS AND USAGE

ALYACEN 1/35 (Norethindrone and Ethinyl Estradiol Tablets USP, 1 mg / 0.035 mg) is indicated for the prevention of pregnancy in women who are using the combination as their method of contraception. It should be administered as follows:

- Take one tablet every day until Sunday. On Sunday the patient should throw out the rest of the pack and start a new one.

Complete instructions to facilitate patient counseling on proper pill usage may be found in the Detailed Patient Labeling (“How to Use the Pill”).

CONTRAINDICATIONS

The following conditions are considered contraindications to the use of oral contraceptives:

- Pregnancy
- Breastfeeding
- Known or suspected liver tumor
- Known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal vaginal bleeding
- Known or suspected hypersensitivity to any component of the product

PRECAUTIONS

This product has not been studied in women over 65 years of age and is not indicated in this population.

REFERENCES

How to use your pill:

1. **Periodic abstinence**
   - You should abstain from sexual contact during your menstrual period. This method is effective only if your menstrual cycle is regular and you know when it begins. This is not a method that can be used by a woman with irregular menstruation.
   - You should always use a form of contraceptive (such as a condom or spermicide) as a back-up method for these 7 days.

2. **Surgical methods**
   - You can choose from various surgical methods of birth control. When they are taken correctly without missing any pills, the chance of becoming pregnant is minimal. If failure does occur, the risk to the fetus is minimal.

3. **No fertility-control methods**
   - Not using any method of contraception is the least effective method of birth control. If you have sex during your menstrual period, you could get pregnant.
   - You should use a form of contraception (such as a condom or spermicide) as a back-up method for these 7 days.

**You Start Taking Your Pills:**

- **Sunday Start:**
  - Take the first white to off-white "active" pill of the first pack during the first 24 hours of your period.
  - **First 7 pills:**
    - You should continue to take 1 pill every day until Sunday.
    - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
  - **Sunday after your period starts:**
    - Start the pack the same day.

- **Monday Start:**
  - Take the first white to off-white "active" pill of the first pack on Monday. If you begin taking the pill on Monday, skip the first 7 pills.
  - **First 7 pills:**
    - You should continue to take 1 pill every day until Sunday.
    - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
  - **Sunday after your period starts:**
    - Start the pack the same day.

**How to Continue Taking Your Pills:**

-**You Start Taking Your Pills:**
  - **Monday Start:**
    - Take the first white to off-white "active" pill of the first pack on Monday. If you begin taking the pill on Monday, skip the first 7 pills.
    - **First 7 pills:**
      - You should continue to take 1 pill every day until Sunday.
      - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
    - **Sunday after your period starts:**
      - Start the pack the same day.

**If You Missed Your Period:**

- **You Start Taking Your Pills:**
  - **Monday Start:**
    - Take the first white to off-white "active" pill of the first pack on Monday. If you begin taking the pill on Monday, skip the first 7 pills.
    - **First 7 pills:**
      - You should continue to take 1 pill every day until Sunday.
      - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
    - **Sunday after your period starts:**
      - Start the pack the same day.

**What to Do If You Missed a Pill:**

1. **Monday Start:**
   - Take the missed pill(s) as soon as you remember, but no later than 12 hours after your usual time. Then take your next pill as usual.
   - **First 7 pills:**
     - You should continue to take 1 pill every day until Sunday.
     - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
   - **Sunday after your period starts:**
     - Start the pack the same day.

2. **Sunday Start:**
   - Take the missed pill(s) as soon as you remember, but no later than 12 hours after your usual time. Then take your next pill as usual.
   - **First 7 pills:**
     - You should continue to take 1 pill every day until Sunday.
     - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
   - **Sunday after your period starts:**
     - Start the pack the same day.

**What to Do About the Pills You Have Missed:**

1. **Keep Taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.**

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**If you are a Sunday Starter:**

- **Sunday Start:**
  - Take the first white to off-white "active" pill of the first pack during the first 24 hours of your period.
  - **First 7 pills:**
    - You should continue to take 1 pill every day until Sunday.
    - On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
  - **Sunday after your period starts:**
    - Start the pack the same day.

**If you are not a Sunday Starter:**

- **Monday Start:**
  - Take the first white to off-white "active" pill of the first pack on Monday. If you begin taking the pill on Monday, skip the first 7 pills.
  - **First 7 pills:**
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