STRAIGHT TALK

COUNSELING PATIENTS ABOUT
EXTERNAL GENITAL AND PERIANAL WARTS (EGW)
General Facts about EGW

“You probably have a lot of questions about external genital and perianal warts, known as EGW. Here is what I tell all my patients when they are diagnosed for the first time.”

• EGW is caused by a virus known as the human papillomavirus (HPV), which is spread by sexual contact with a person who is infected. \(^{15}\)

• HPV is very common: most sexually active people will get the virus at some point in their lives –although most will never know it because HPV infection usually has no signs or symptoms. \(^{2}\)

• HPV can affect anyone, regardless of age, race or gender. \(^{15}\)

• EGW is the most common sexually transmitted disease (STD) in the United States. \(^{3}\)

• Warts may appear weeks, months or even years after exposure, or they may never appear. \(^{15}\)

• If you have warts, they may shed the virus - seeking treatment is critical to minimize the risk of passing on the infection. \(^{15}\)

• Warts often go away without treatment. But even if your warts have disappeared or have been removed, you can still harbor HPV and may transmit the virus to others. \(^{10}\)

• EGW are not life-threatening. Except in very rare and unusual cases, genital warts will not turn into cancer. \(^{4}\)

VEREGEN® is indicated for the topical treatment of external genital and perianal warts (Condylomata acuminata) in immunocompetent patients 18 years and older.

Important Selected Safety Information

VEREGEN® has not been evaluated to treat urethral, intra-vaginal, cervical, rectal, or intra-anal human papilloma viral disease and should not be used to treat these conditions. Avoid use of VEREGEN® on open wounds. Please see additional Important Selected Safety Information on page 4. Please see accompanying full Prescribing Information.

Emotional Impact/How to Talk to Your Partner

“These are the most common questions I get from patients when they are first diagnosed with EGW.”

• How could I have gotten infected?
• How quickly will it go away?
• What do I tell my partner?
• Can I have sex?
• How do I have safe sex?

“To answer these questions, I offer the following information and recommend that patients share it with their partner(s).”

• EGW is spread by unsafe sexual contact with a person infected with HPV. One main risk factor that increases a person’s chances of becoming infected is having multiple sex partners, or having sex with someone who has had many sex partners.

• Most EGW respond within three months of treatment. If visible warts have cleared – whether after treatment or on their own – I may still want to see you again to monitor for recurrences and/or to treat possible side effects. Regardless, we’ll be in touch throughout the course of therapy to see how you’re doing.

• EGW is contagious, so you should inform your sexual partner(s) that you have the virus.
  – It’s important that you are up front about it. Let your partner know you are discussing this because you care. Emphasize the positive fact that you are being honest, even though it is hard.
  – Explain that your diagnosis does not mean that you have been unfaithful. There is no sure way to know when you became infected or who gave it to you.
  – Your partner may feel emotional and confused. Reassure them by providing as many facts about the condition as possible. For instance, explain that treatment can clear up visible EGW, although the virus itself has no cure and may remain in skin.
  – Strongly recommend that your partner be seen by a healthcare professional for an examination and for more information. Screening and/or treating your partner is essential in order to prevent reinfection and to prevent infecting future partners.

• You should wait to have sex for at least two weeks after the warts have gone away and the area has visibly cleared.

• You should use safe-sex strategies, such as consistent condom use, that includes coverage of any EGW sites, to reduce the chances of HPV. However, no method of prevention is 100 percent effective other than abstinence.

What is your patient thinking?

“What do I tell my boyfriend?”

“Can you keep this between us?”
Implications – Known and Unknown

“Some of my patients believe EGW, or any STD for that matter, is a minor nuisance rather than a chronic illness that they can pass on to others. I like to give my patients all the facts so they can make an informed decision about their care.”

- If left untreated, EGW may itch, bleed, spread to nearby areas or grow larger, potentially interfering with bowel movements and urination. The longer EGW remains active, the harder it is to treat it.
- Untreated EGW may cause problems during pregnancy. Warts on the vaginal wall may cause changes that reduce the stretching ability of vaginal tissues during childbirth. There is a very low risk that a pregnant woman with EGW can pass HPV to her baby.
- Many people whose warts have visibly cleared through treatment are under the misperception that they are cured. However, treating EGW will not necessarily lower your risk of passing HPV to a sex partner, since the virus can still remain in your skin at the site of infection.
- Treatment may result in skin discoloration or flat or depressed scars. Treatment may also cause bacterial infections on or around the anus or rectum.
- Because EGW is a virus (like herpes) that can remain dormant but alive in affected skin, preventing a recurrence is an important consideration, as is recognizing and promptly treating a recurrence.

Treatment Objectives

“Many patients believe that treatment will permanently eliminate the warts, and they will never have to deal with the problem again. Unfortunately, that is not the case. There is no cure for EGW; as a result, warts often return after treatment is completed. The primary goal of treatment is to remove the warts and relieve symptoms. An ideal outcome is complete clearance of all warts with a low likelihood for recurrence.”

- I realize you may want to take care of your EGW immediately, but it’s important to think through which option might be appropriate for you.
- There are several considerations when choosing a treatment. In my experience, patients are most interested about:
  - side effects – is the treatment painful?
  - the speed of treatment – how fast does it work?
  - overall effectiveness – how well does it work in the short- and long-term?
  - the duration of treatment – how long will I need to be on the medication?
  - access issues – do I need to come back for repeat treatments, and will it be covered by insurance?
  - total cost
  - time until next doctor’s appointment (some treatments require more regular doctor visits than others)

Important Selected Safety Information

Avoid exposure of VEREGEN®-treated areas to sun/UV-light because VEREGEN® has not been tested under these circumstances. Safety and efficacy of VEREGEN® have not been established in immunosuppressed patients or patients under 18 years of age, or pregnant women, or for the treatment of external genital and perianal warts beyond 16 weeks or for multiple treatment courses. The most common adverse reactions are local skin and application site reactions including (incidence ≥ 20%) erythema, pruritus, burning, pain/discomfort, erosion/ulceration, edema, induration, and rash vesicular. Please see additional Important Selected Safety Information on page 2. Please see accompanying full Prescribing Information.
Deciding on the Course of Treatment

“There are a number of treatments available for EGW. Treatments are divided into two types: provider-applied and patient-applied. Each treatment type has its pluses and minuses and all may be effective for the appropriate patient if the regimen is properly adhered to.”

- Patient-applied treatments offer the advantages of convenience and privacy. These treatments include prescription creams, gels and ointments that you apply directly to the affected skin at home. To get the best results, you must be able to see and reach all of the warts and carefully follow prescribing directions.
- Physician-applied treatments include surgical and non-surgical procedures administered at the healthcare professional’s office or clinic.

EGW Treatment Options

Note: This chart gives you a quick “at-a-glance” look at the various EGW treatment options. We can discuss each of these options in depth to help you decide which is “best” for you. An acceptable alternative for some persons is to forego treatment and wait for spontaneous resolution. For more information on EGW treatment options reference the CDC STD Treatment Guidelines at, http://www.cdc.gov/std/treatment/2010/default.htm

### Patient-Applied

<table>
<thead>
<tr>
<th>Treatment/method</th>
<th>Description</th>
<th>Dose/Route</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Condylox® (podofilox) liquid/gel</strong></td>
<td>Works to destroy genital wart tissue⁹</td>
<td>Apply 2x/day for 3 days, rest 4 days, 4 cycles max.</td>
</tr>
<tr>
<td></td>
<td>The exact mechanism of action is unknown¹⁶</td>
<td></td>
</tr>
<tr>
<td><strong>Aldara® or Zyclara® (imiquimod) cream</strong></td>
<td>May boost the body’s immune system to fight EGW¹⁰</td>
<td>Aldara®: Apply 1x/day, 3x/week, no consecutive days, 16 weeks max. Zyclara®: Apply 1x/day, 8 weeks max.</td>
</tr>
<tr>
<td></td>
<td>The exact mechanism of action is unknown¹⁷¹⁸</td>
<td></td>
</tr>
<tr>
<td><strong>VEREGEN® (sinecatechins) Ointment</strong></td>
<td>“Botanical drug” derived from green tea leaves¹¹</td>
<td>Apply 3x/day, 16 weeks max.</td>
</tr>
<tr>
<td></td>
<td>The mode of action involved in the clearance of EGW is unknown¹²</td>
<td></td>
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</tbody>
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### Provider-Applied

<table>
<thead>
<tr>
<th>Treatment/method</th>
<th>Description</th>
<th>Dose/Route</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cryotherapy</strong></td>
<td>Liquid nitrogen is used to freeze off EGW¹³</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Electrocautery</strong></td>
<td>Low-voltage electricity is used to burn off EGW¹³</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Surgical excision</strong></td>
<td>Scalpel or other cutting instrument is used to remove EGW¹³</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Laser surgery</strong></td>
<td>Intense beam of light is used to destroy EGW¹³</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Chemical treatments</strong></td>
<td>Non-surgical chemical agent is used to destroy EGW¹⁰,¹³</td>
<td>Apply small amount, dry, apply weekly if necessary</td>
</tr>
</tbody>
</table>
Follow-up Visits With Currently Diagnosed Patients

During follow-up visits, you can educate patients about how to incorporate management of external genital and perianal warts (EGW) into their daily lives. Suggested discussion topics include:

1) patient follow-up to help ensure treatment effectiveness
2) continued monitoring

Lifestyle Modifications and Behavior Change

“As I tell all my patients, you have the ability to successfully manage your EGW and reduce the risk of passing it on to others. Continue to communicate with your partner and adopt lifestyle changes to maintain your health and well-being.”

- As with other viral infections, you’re less likely to experience EGW recurrences if you take care of your health. This means that you want to maintain a strong immune system by eating right, exercising regularly, getting enough sleep, managing stress, and avoiding alcohol, tobacco and illegal drugs.
- Remember that even without visible symptoms, you can still pass HPV on to others.
- Some proven strategies to reduce the risk of transmission include:
  1) a monogamous relationship with an uninfected partner
  2) limiting the number of sex partners
  3) barrier protection (such as a male or female condom that includes coverage of any EGW sites)
  4) abstinence

Careful Monitoring and Compliance with Treatment

“The most important thing you can do for your health is to continue to have regular check-ups. Continue to examine your genitals regularly to check for warts and to have annual physical exams.”

- Continue to check for recurrence of EGW. Some patients may need repeat treatments if the warts return.
- Schedule a follow-up exam so we can check for any new warts or growths that you can’t see.
- It may take several visits to your healthcare provider and a variety of approaches to completely clear your EGW. Make sure you keep all your appointments and follow your treatment regimen.
References


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