

BENLYSTA and Your Child

A caregiver's resource



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BENLYSTA and Your Child

A caregiver's resource

Bumps, scrapes, and bruises. They're all a natural part of childhood, usually remedied by a kiss, a cute bandage, and a cookie. But, as you know, lupus is different and your child needs special support.

When your child's been diagnosed with lupus—and the treatment plan includes infusions of BENLYSTA—you may be feeling fear, uncertainty, and worry. And while your child's treatment isn't the same as with everyday childhood boo-boos, your love and support does remain the same. **That's why we're here, with information and tips just for you as you care for a child with lupus. Remember, too, that your child's doctor can help with any of your questions or concerns.**



What is BENLYSTA?

BENLYSTA is a prescription medication used to treat patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines. Intravenous dosing of BENLYSTA is approved for adults and children aged 5 years and older. Subcutaneous dosing of BENLYSTA is only approved for adult patients.

It is not known if BENLYSTA is safe and effective in people with severe active lupus nephritis or severe active central nervous system lupus, and it has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of BENLYSTA is not recommended in these situations.

Do not receive BENLYSTA if you are allergic to belimumab or to any of the ingredients in BENLYSTA.

Important Safety Information

The most important information to know about BENLYSTA

BENLYSTA can cause serious side effects. Some of these side effects may cause death. It is not known if BENLYSTA causes these serious side effects.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Understand BENLYSTA (belimumab)

You and your child's doctor have chosen to add BENLYSTA IV to your child's treatment plan. Did you know it's the only biologic approved for the treatment of children 5 years and older with lupus? It can be used in patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines.

Why BENLYSTA?

BENLYSTA is the first FDA-approved treatment for lupus in over 50 years in both adults and children as young as 5 years old. It has been prescribed in over [58,000] adult patients.* And it has the largest lupus clinical trial program to date, including one study in pediatric patients.

*Source: Symphony Health, PayerSource, March 2011 to [December 2018]. Claims data based upon total unique number of patients who had at least one claim for BENLYSTA in the US only.

In a pediatric study, when added to other medicines commonly used to treat lupus, compared to those medicines used alone, BENLYSTA given to children has been observed to:

- Reduce lupus disease activity[†]
- Reduce the chance of severe flares[†]

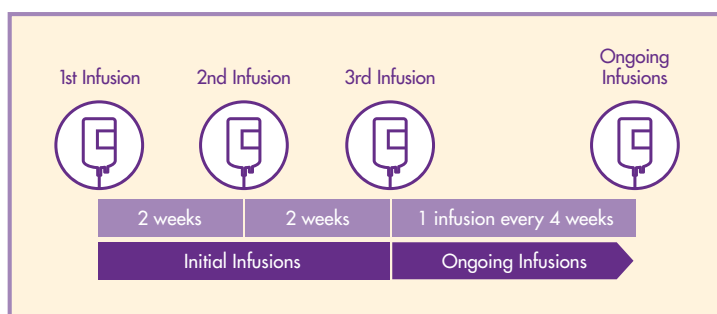
[†]Because lupus doesn't occur in children very often, the pediatric study had a much smaller number of patients than the adult studies of BENLYSTA. The study in children was still able to support that BENLYSTA worked, with results similar to those from the adult studies. Due to the small size of the study, however, there was no way to confirm the effect or the consistency of the results.

Please note that these are findings based upon a study in pediatric patients. Your child's individual results may vary.

How BENLYSTA is administered to children

For children ages 5 and above, BENLYSTA can be administered by your healthcare provider through an IV infusion. It is given every 2 weeks for the first three doses and then at 4-week intervals thereafter.

It is given to your child by a healthcare provider through a needle placed in a vein. This infusion process takes about 1 hour. Preparation time before and observation time after the infusion may vary.



Get to know the infusion center

You may have questions

Whether you and your child will be visiting a doctor's office, a hospital, or a dedicated infusion center, be sure to ask any questions you have. Every infusion center is different and has its own policies. Below are suggested topics to discuss with the center:



Should you talk to the nurses? No matter where your child receives infusions, the staff is there for each of you. Feel comfortable discussing any of your concerns. In fact, a strong relationship built on honest communication can go a long way toward making your family's experience more positive.



Should you talk to other patient families? Speaking with others at the infusion center can be a good idea. They may have tips, and you may make new friends! Approach conversation as you would any other public place, taking your cues from those around you.



Is it OK to take siblings? Sometimes life happens—and that may mean having siblings along for your child's infusion. Be sure to check with the staff about having other children in the infusion room with you. As with any medical appointment or typically "adult" space, make sure you have plenty of activities for all your children, such as movies to watch or pages to color.



Is it OK to talk on the phone? As with most public places, it's usually not a good idea to talk on the phone. If you must take a phone call, be sure to check with someone, since every institution has its own policies.



Should you take snacks or drinks? Having treats to eat and drink makes almost any situation a bit better! But be sure to ask the staff at your center about their policy. Most will allow you to have water and a snack.

Important Safety Information (cont'd)

Tell your healthcare provider right away if you have any of the symptoms listed below while receiving BENLYSTA

- **Infections:** fever, chills, pain or burning with urination, urinating often, coughing up mucus, or warm, red, or painful skin or sores on your body.
- **Heart problems:** chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, or discomfort in other areas of the upper body.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

What your child may experience

Your family's time at the infusion center will vary, but your experience may include the following:

- You may be asked to arrive early to complete any paperwork.
- As your child is prepped for their infusion, they may be asked how they're feeling. You may also be asked for some of their medical history.
- Your child may have their vital signs taken, such as temperature and blood pressure.
- Your child may be given medication to help reduce the chance of an allergic reaction. It is not known if these medications will help reduce the chance of an allergic reaction to BENLYSTA (belimumab).
- Your child's arm or hand will be prepared for the IV infusion.
- Your child's vital signs will be monitored regularly.
- Your child will spend about an hour in the infusion chair.



Notify the staff immediately if you notice—or your child tells you—they're not feeling "right" at any point during your infusions. Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death. Your child's healthcare provider will watch your child closely while they are receiving BENLYSTA given intravenously (infusion) and after their infusion for signs of a reaction. Allergic reactions can sometimes be delayed. Tell their healthcare provider right away if they have any of the symptoms of an allergic reaction (shown on the next page) following use of BENLYSTA.

Tips for your child's infusion time

As your child receives their infusions, keep in mind:

You may see different staff members at each infusion.

They're all there for your child's safety and comfort. Feel free to ask questions and share your feelings and concerns with any of them.

Don't assume the staff knows your child's entire medical history.

Being open and honest is important for their health—and may help you both feel more confident and comfortable with the infusion process.

At your child's first infusion, make notes for the next time.

Was your child too hot or too cold? Wish you had remembered their favorite stuffed animal? Add to the packing list on page 9 or make a list on your phone.

The staff at the center can help in many ways.

Don't hesitate to reach out to them. They can give you guidance on medical questions, billing, appointments, and more.

Important Safety Information (cont'd)

Tell your healthcare provider right away if you have any of the symptoms listed below while receiving BENLYSTA (cont'd)

- **Allergic (hypersensitivity) reactions:** itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, or skin rash. Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death.
- **Mental health problems and suicide:** thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety or depression, acting on dangerous impulses, other unusual changes in your behavior or mood, or thoughts of hurting yourself or others.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Prepare your child

Start by talking about lupus

Your child may have already been living with lupus for a while. But as they get older, how you talk about lupus and the questions your child may have will change. Make sure what you say is appropriate for your child's age and maturity level.

No matter their age, all children living with lupus should know:

- It's not their fault they have lupus. Nothing they did or didn't do caused it.
- Lupus is not contagious. It can't be given to someone else.
- Lupus might make them feel tired, sore, and achy. Encourage your child to listen to what their body is telling them and to tell you, or another adult (such as a teacher or coach), anytime they're not feeling well.
- You and your child can work together to help their teachers, coaches, classmates, and friends understand about their lupus. It may be hard, but it's important so they can better understand what your child is going through.
- There will be times when your child feels okay and times when lupus makes them feel sick. Those sick times are called "flares."
- Work with your child and their doctors to learn ways to better manage their lupus and keep them as healthy as possible.



Get help from a professional

Coping with a chronic illness can be tough for anyone at any age. Your child may experience a range of emotions about lupus—and its impact on their life. You may want to ask your child's doctors for advice.

Talk about the infusion experience

Your child is old enough to understand that medicine is an important part of treating illnesses. Still, BENLYSTA (belimumab) may be the first medication your child has received by IV infusion. Before your child's first appointment, talk about what they may experience in a simple, straightforward way.



Take a moment to reassure your child that you'll be by their side during the IV insertion. You may even want to help distract your child from the needle-stick by:

- Telling stories
- Holding their hand or having them sit on your lap
- Praising them for any successes, such as holding their arm still
- Making funny faces at each other
- Talking about their favorite subject at school
- Singing softly
- Rubbing your child's arm or leg

Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you:

- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your healthcare provider tells you to.
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Plan and pack

After you've talked to your child about what to expect at their infusion, have them imagine staying relaxed, calm, and still during the procedure. Ask, "Do you think you want to watch and learn as the IV is inserted? Or would you rather look away?"

If your child wants to watch and learn, let them know they can:

- Ask to hear about each step before it happens, or as it happens.
- Ask the nurse what they can do to help.
- Take slow, deep breaths.
- Have someone hold their other hand.

Children who prefer to look away can:

- Ask the nurse to cover the IV supplies.
- Take a toy or book from home to look at.
- Look at something else in the room or close their eyes.
- Take slow, deep breaths.
- Have someone hold their other hand.

Knowing how your child might like to approach the infusion can help you plan and pack for their first appointment.

A few days before Have your child choose a tote bag or backpack for their infusion time. Then pack it with anything you might need for the appointment.

Talk to your child about what they want to take along for comfort and reassurance. It may be a small pillow, a fuzzy blanket, or a favorite stuffed animal.



Your child will have about an hour to wait while receiving BENLYSTA (belimumab). Plan how you want to spend that time together. Coloring books and movies may be good choices for your family. Older kids may want to take homework or a laptop for video games. We've included a few activity pages after this guidebook for you to use.

The night before Since you can't be sure that you'll have access to an outlet, charge your child's tablet, phone, or laptop fully before you head to the infusion center. You may even want to have a portable phone charger ready to go!

Talk to your child's doctor about things you may want to do the day before their infusion.

Finally, have your child pick out what they want to wear. Help them choose an outfit that's comfortable. Make sure, too, that they wear a shirt with sleeves that can be pushed or rolled up.



Infusion packing list

- | | |
|----------------------------------|--------------------------------|
| ___ Snacks | ___ Coloring or activity books |
| ___ Water | ___ Books to read |
| ___ Blanket/small pillow | ___ Homework |
| ___ Stuffed animal | ___ Included activity pages |
| ___ Tablet or laptop | _____ |
| ___ Headphones | _____ |
| ___ Portable charger (and cords) | _____ |
| ___ Crayons, pencil, markers | _____ |

Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you: (cont'd)

- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies, or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- have any other medical conditions.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

After an infusion of BENLYSTA (belimumab)

Right after the infusion

Before you leave the infusion center, it's important to remember a few things:

- Make sure you understand any post-infusion instructions the staff gives you.
- Schedule at least your child's next three infusion appointments.
- Depending on how your child feels, they may be able to return to normal activities right away.
- If given a pre-infusion medication, your child may feel drowsy for a number of hours after their infusion.

What to look out for in the coming days

If you have any questions or are worried about anything, reach out to your child's healthcare team.

- If your child doesn't feel well or has any soreness or tenderness at the infusion site that doesn't go away, contact their doctor.
- Be aware of any symptoms of an allergic or infusion reaction. These may include itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, or skin rash. Tell your child's doctor or get emergency medical help right away if your child has any of these symptoms.

Review with your child

Take some time in the days following your child's infusion to review their experience. Was anything surprising or scary? What are they—and you—proud of? Did they enjoy the activities they packed? Were they too warm or too cool? Make note of anything you'd like to do differently next time here in this guidebook or in your phone.

Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you: (cont'd)

- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your healthcare provider about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA. Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Look ahead

Before the next infusion

Before your child's next infusion, review any notes you've written down in this guidebook. Look over any additions to the packing list on page 9 to see what you need to remember to take next time.

Continue the commitment

Remember, every patient responds differently to BENLYSTA. Talk to your child's doctor about any questions you may have about their treatment.

Do not skip your child's infusions unless directed by their doctor. It's important for your child to continue to receive BENLYSTA as prescribed, even if they are feeling better.

Find ongoing support

Did you know we're here to help, too? We're committed to giving your family support for everyday living, working with your child's healthcare team, helping you understand your insurance coverage for BENLYSTA through BENLYSTA Gateway, and much more—every step of the way.

To get started right away, to speak to our trained nurses,* or to get more information about BENLYSTA, call us at **1-877-4-BENLYSTA** (1-877-423-6597).

*Nurses from BENLYSTA Cares do not give medical advice. They are only able to answer questions about BENLYSTA. These may include help with self-injections, guidance for getting BENLYSTA, answers about the co-pay program, and other general information. They will direct you to your healthcare provider for answers to other types of questions. Nurses are available by phone Monday - Friday, 8 AM - 8 PM, Eastern Time. If calling after hours, please leave a message and a nurse will return your call within 30 minutes.



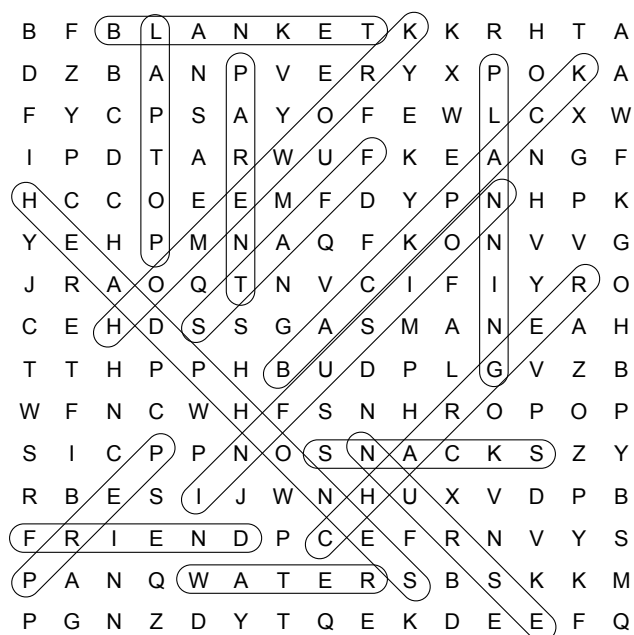
Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you: (cont'd)

- become pregnant while receiving BENLYSTA. Talk to your healthcare provider about enrolling in the BENLYSTA Pregnancy Registry. You can enroll in this registry by calling 1-877-681-6296. The purpose of this registry is to monitor the health of you and your baby.
- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your healthcare provider should talk about whether or not you should receive BENLYSTA and breastfeed.

Please see additional Important Safety Information continued on the following pages and accompanying Important Facts About BENLYSTA.

Answer key



1	4	7	2	5	8	3	6	9
8	9	3	1	6	7	4	2	5
2	5	6	4	9	3	1	7	8
3	1	9	5	4	6	2	8	7
4	6	5	7	8	2	9	1	3
7	2	8	9	3	1	5	4	6
5	8	2	6	1	9	7	3	4
6	7	4	3	2	5	8	9	1
9	3	1	8	7	4	6	5	2

Important Safety Information (cont'd)

Possible side effects of BENLYSTA

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. PML can result in death or severe disability. Tell your healthcare provider right away if you notice any new or worsening medical problems: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, or loss of vision.
- **Cancer.** Medicines that affect the immune system, including BENLYSTA, may increase your risk of certain cancers.

The most common side effects of BENLYSTA are nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection (when given subcutaneously). These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying Important Facts About BENLYSTA.

Have questions or need assistance?

BENLYSTA
Cares

Call 1-877-4-BENLYSTA
(1-877-425-6597)

Insured

Underinsured

Uninsured

Whether you are insured, underinsured, or uninsured, BENLYSTA Cares and our team at BENLYSTA Gateway may be able to help.

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Produced in USA. 0002-0006-82

Benlysta
(belimumab)
Intravenous Use 120 mg/vial



IMPORTANT FACTS ABOUT BENLYSTA

The risk information presented here is not comprehensive. To learn more, talk to your healthcare provider (HCP). Visit www.BENLYSTA.com or call 1-877-423-6597 to get FDA-approved product labeling, including Medication Guide.

What is the most important information I should know about BENLYSTA?

BENLYSTA can cause serious side effects. Some of these side effects may cause death. It is not known if BENLYSTA causes these serious side effects. Tell your HCP right away if you get any of the following signs or symptoms while receiving BENLYSTA:

- **Infections.** Symptoms can include: fever, chills, pain or burning with urination, urinating often, coughing up mucus, warm, red, or painful skin or sores on your body.
- **Heart problems.** Symptoms can include: chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, discomfort in other areas of the upper body.
- **Allergic (hypersensitivity) reactions.** Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death. Symptoms can include: itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, skin rash.
- **Mental health problems and suicide.** Symptoms can include: thoughts of suicide or dying, attempt to commit suicide, trouble sleeping, new or worse anxiety, new or worse depression, acting on dangerous impulses, other unusual changes in your behavior or mood, thoughts of hurting yourself or others.

What is BENLYSTA?

BENLYSTA is a prescription medicine used to treat patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines. Intravenous dosing of BENLYSTA is approved for adults and children aged 5 years and older. Subcutaneous dosing of BENLYSTA is only approved for adult patients.

It is not known if BENLYSTA is safe and effective in people with severe active lupus nephritis or severe active central nervous system lupus.

Who should not use BENLYSTA?

Do not use BENLYSTA if you are allergic to belimumab or any of the ingredients in BENLYSTA.

What should I tell my HCP before receiving BENLYSTA?

Before you receive BENLYSTA, tell your HCP about all of your medical conditions, including if you:

- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your HCP tells you to. **See “What is the most important information I should know about BENLYSTA?”**
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies, or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your HCP about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA. Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.

- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your HCP should talk about whether or not you should receive BENLYSTA and breastfeed.

Tell your HCP about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of BENLYSTA?

BENLYSTA can cause serious side effects including:

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. Your chance of getting PML may be higher if you are treated with medicines that weaken your immune system, including BENLYSTA. PML can result in death or severe disability. Tell your HCP right away if you notice any new or worsening medical problems such as: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, loss of vision.
- **Cancer.** BENLYSTA may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.

The most common side effects of BENLYSTA include: nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection.

These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Keep BENLYSTA and all medicines out of reach of children.

CYTOXAN is owned by Baxter International Inc. BENLYSTA is owned by or licensed to the GSK group of companies.

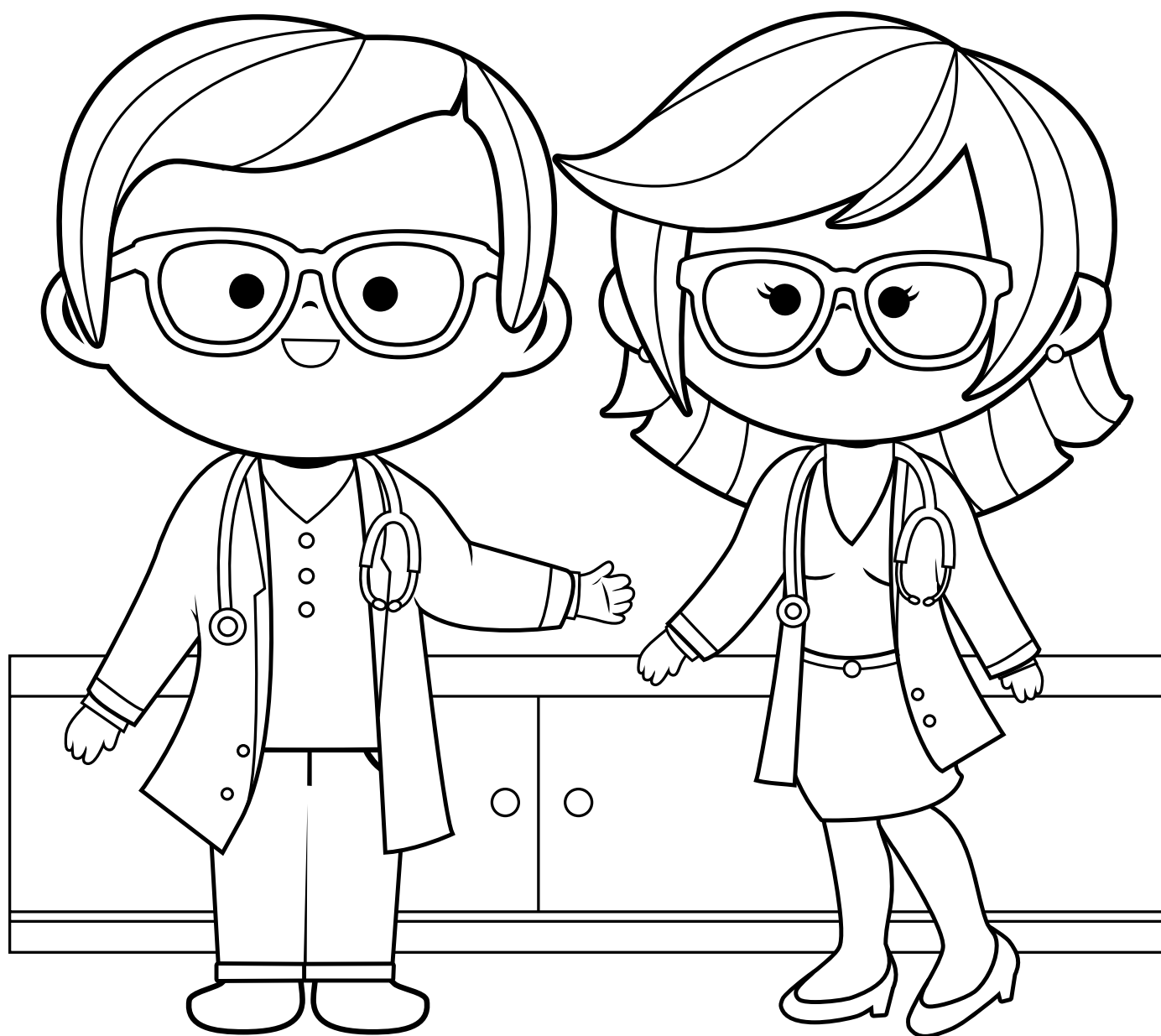


GlaxoSmithKline
Research Triangle Park, NC 27709

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Color it

Use your favorite colors to decorate this picture.



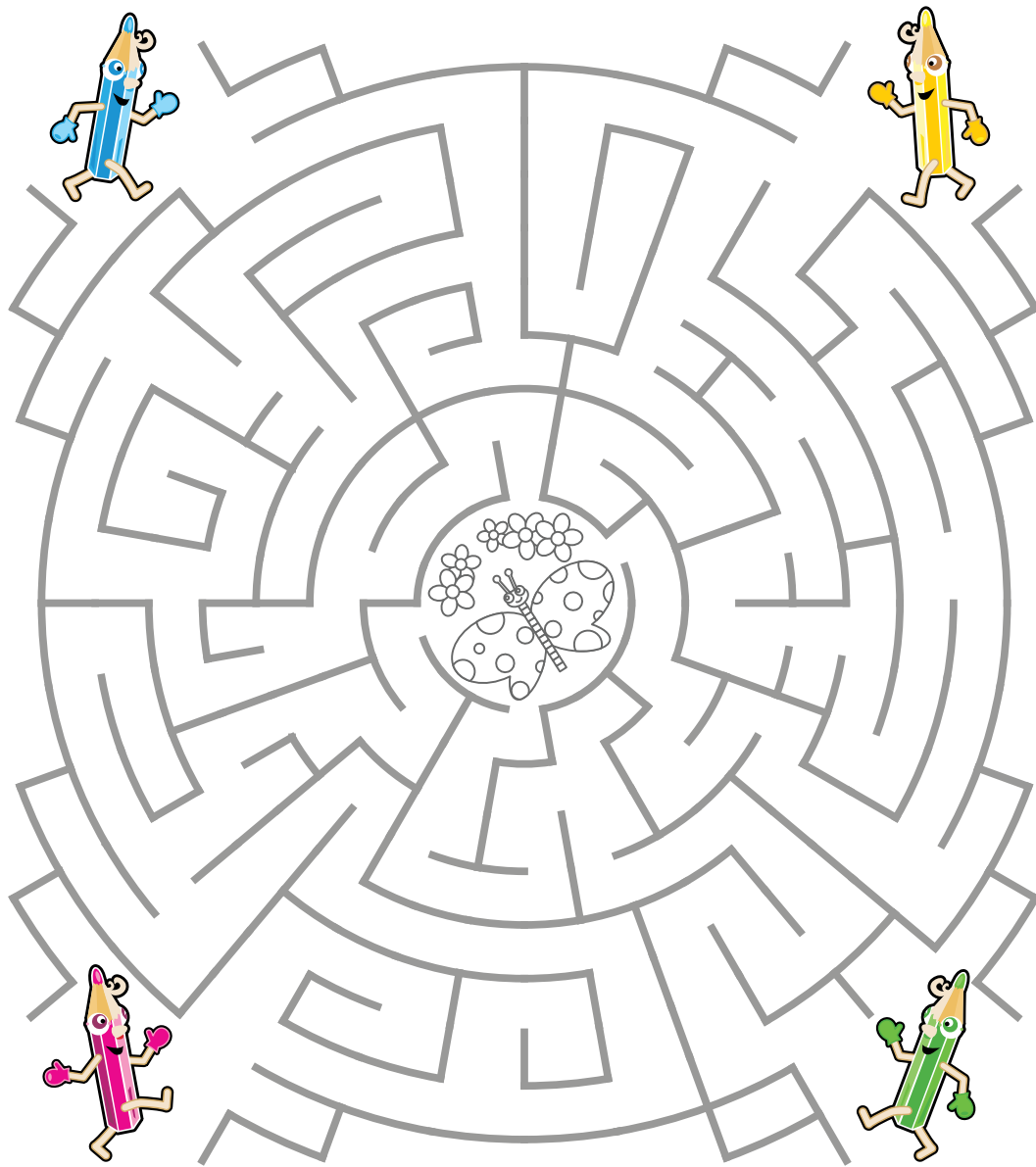
Connect the dots

Count from 1 to 55 to find a special shape.



Help the pencils find their way

Draw to get each pencil to the middle of the maze. Then color the butterfly and flowers.



Solve it

Fill in the squares so that the numbers 1–9 appear just one time in each column, each row, and each 3x3 box.

	4		2			3	6	
	9				7	4	2	
		6			3			8
3		9	5			2		
			7		2		1	
7		8				5		
				1	9		3	
	7	4					9	1
		1	8		4	6		

Color it

Use your favorite colors to decorate this butterfly.



Find it

Look for the words from the list and circle them in the grid.

B	F	B	L	A	N	K	E	T	K	K	R	H	T	A
D	Z	B	A	N	P	V	E	R	Y	X	P	O	K	A
F	Y	C	P	S	A	Y	O	F	E	W	L	C	X	W
I	P	D	T	A	R	W	U	F	K	E	A	N	G	F
H	C	C	O	E	E	M	F	D	Y	P	N	H	P	K
Y	E	H	P	M	N	A	Q	F	K	O	N	V	V	G
J	R	A	O	Q	T	N	V	C	I	F	I	Y	R	O
C	E	H	D	S	S	G	A	S	M	A	N	E	A	H
T	T	H	P	P	H	B	U	D	P	L	G	V	Z	B
W	F	N	C	W	H	F	S	N	H	R	O	P	O	P
S	I	C	P	P	N	O	S	N	A	C	K	S	Z	Y
R	B	E	S	I	J	W	N	H	U	X	V	D	P	B
F	R	I	E	N	D	P	C	E	F	R	N	V	Y	S
P	A	N	Q	W	A	T	E	R	S	B	S	K	K	M
P	G	N	Z	D	Y	T	Q	E	K	D	E	E	F	Q

BACKPACK

FRIEND

INFUSION

PARENT

SNACKS

BLANKET

HEADPHONES

LAPTOP

PLANNING

STAFF

CHARGER

HOMEWORK

NURSE

PREP

WATER