# GETTING CLOSER TO YOUR GOALS

Talk to your doctor and learn about a treatment option for spasticity that may complement your physical or occupational therapy.



#### What is Dysport?

Dysport is a prescription medicine that is injected into muscles and used to treat:

- increased muscle stiffness in patients 2 years of age and older with upper and lower limb spasticity
- cervical dystonia (CD) in adults

### IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport?

Dysport may cause serious side effects, including problems breathing or swallowing and/or spread of toxin effects, that can be life threatening and death can happen as a complication. These problems can happen within hours, or days to weeks after an injection of Dysport.



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#### IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport? (continued)

- Problems swallowing, breathing, or speaking. Treatment with Dysport can result in swallowing or breathing problems. People with pre-existing swallowing or breathing problems may be at greater risk following treatment with Dysport. Swallowing problems may last for several weeks; you may need a feeding tube to receive food or water. If swallowing problems are severe, food or liquids may go into your lungs.
- Spread of toxin effects. The effects of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism which include: loss of strength and muscle weakness all over the body, double or blurred vision, and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, and trouble breathing or swallowing. The risk of these symptoms is probably greatest in children treated for spasticity. These problems could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

Call your doctor or get medical help right away if you experience these problems after treatment with Dysport.

## Finding the right treatment plan

As you may know, living with spasticity can be a challenge. Like many people with this condition, your muscles may regularly contract or tense up, leading to tightness or abnormal positioning.

You may have stiffness and spasms in your arms (which is known as upper limb spasticity or ULS), your legs (lower limb spasticity or LLS), or both.



Fortunately, the right therapy path may help people living with spasticity get closer to their treatment goals.

In this brochure, you'll learn about a medication that a specialist may want to add to your current treatment plan to help you reach yours.

## IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport? (continued)

Do not receive a Dysport injection if: you are allergic to Dysport or any of its ingredients, or cow's milk protein; you had an allergic reaction to any other botulinum toxin product, such as Myobloc®, Botox®, or Xeomin®; or you have a skin infection at the planned injection site.

#### Before you receive a Dysport injection tell your doctor:

About all your medical conditions, including if you have a disease that affects your muscles
and nerves (such as ALS or Lou Gehrig's disease [amyotrophic lateral sclerosis], myasthenia
gravis, or Lambert-Eaton syndrome). You may be at increased risk of serious side effects,
including difficulty swallowing or breathing.





## Why a botulinum toxin may help

There are a few types of treatment options for spasticity. In addition to physical therapy (PT) or occupational therapy (OT), you may receive an oral medication as part of your spasticity management plan.

However, if you still have symptoms, ask your doctor if Dysport® (pronounced DIS-port) is an appropriate treatment option for you. Dysport is a botulinum neurotoxin, also known as a botulinum toxin, or simply, a toxin.

Dysport is given as an injection and should be administered by a doctor or other healthcare provider who has been trained for this type of treatment. Dysport is given no fewer than every 3 months to improve muscle tone and help reduce stiffness.



#### IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

• If you have or have had any of the following: a side effect from any botulinum toxin in the past; problems with breathing such as asthma or emphysema; swallowing; bleeding; diabetes; and slow heartbeat, or problems with your heart rate or rhythm.

## What is Dysport?

Dysport is an FDA-approved prescription medication that is indicated for both adult ULS (upper limb spasticity) and adult LLS (lower limb spasticity). Dysport works by temporarily blocking the signals in the brain that cause muscles to tighten or contract.



If you and a specialist decide that Dysport may be right for you, here's what may happen during a typical office visit:

- Dysport is given as an injection into affected muscles for which Dysport is approved
- Depending on how many muscles are affected, you may receive injections in a few different muscles
- A specialist may tailor the number of injections, or dose of Dysport, to your needs

After Dysport is injected in your muscles, those muscles are relaxed for up to 12 to 16 weeks or longer.\* This may help lessen your symptoms.

Your injection specialist will assess your spasticity at each follow-up treatment session. He or she may continue to adjust the dose and muscles injected.



\* The minimum treatment interval is 12 weeks for adult ULS and adult LLS. However, some patients had a longer duration of response in the clinical study

#### IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

- If you have plans to have surgery, had surgery on your face, have weakness of your forehead muscles (trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks.
- If you are pregnant or breastfeeding or plan to become pregnant or breastfeed. It is not known if Dysport can harm your unborn baby or if it passes into breast milk.









## How Dysport® worked in clinical studies

In clinical studies, Dysport was effective for the majority of adults with ULS and adults with LLS who showed improvement in muscle stiffness at Week 4.

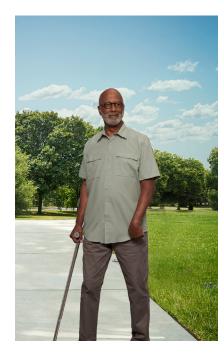


#### Upper limb spasticity

Approximately 3 out of 4 adults with ULS had a response to Dysport at Week 4 as measured by a reduction in stiffness in the elbow, wrist, or finger muscles.

• For most patients, improvement was seen 1 week after treatment

Ask your doctor or injection specialist if Dysport may be right for you.





## Lower limb spasticity

Nearly half of adults with LLS had a response to Dysport at Week 4 as measured by a reduction in muscle stiffness at the ankle joint.

• For most patients, improvement was seen 1 week after treatment



See the last page of this brochure for more details.



#### Time to retreatment for ULS or LLS

In the clinical studies, most adults needed treatment again between 12 and 16 weeks. Some had a longer response and were treated again at 20 weeks. Your doctor will decide when you are ready for another Dysport treatment session.

#### IMPORTANT SAFFTY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

· About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products. Using Dysport with certain other medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you have received Dysport in the past.

#### Recognize possible side effects

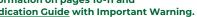
- The most common side effect of Dysport in adults with ULS was muscle weakness.
- The most common side effects of Dysport in adults with LLS include muscle weakness, pain in the arms or legs, and fall.

#### IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

Especially tell your doctor if you have received any other injections of botulinum toxin in the last four months or ever; Myobloc®, Botox®, or Xeomin® (exactly which ones); an antibiotic recently by injection; or if you take muscle relaxants; allergy, cold or sleep medicine.









## Ask your specialist if Dysport® is right for you

A specialist is your best source of information about spasticity and treatment with Dysport. If you are interested in adding a toxin like Dysport to your treatment plan, here is a list of things you may want to ask during your visit:



- · What should I expect from Dysport?
- If we decide that Dysport may be right for me, how will I know it's working?
- · When would I schedule a Dysport treatment session? Can I start today?
- What are the possible side effects of Dysport?
- What other safety information should I know about Dysport?

#### Don't hold back

It's important to be open and honest with your specialist about how you are feeling. Your physical or occupational therapist may have helped you fill out a *Spasticity Treatment Discussion Guide*. If so, remember to bring your guide to your appointment and share your answers with your specialist.



Searching for a trained Dysport injector?
Use our Injector Locator search tool to find one in your area at <a href="Dysport.com/FindInjector">Dysport.com/FindInjector</a>.

See the last page of this brochure for more details.



#### IMPORTANT SAFETY INFORMATION

Most common side effects of Dysport in:

- adults with lower limb spasticity include: fall, muscle weakness, pain in your arms or legs.
- adults with upper limb spasticity include: muscle weakness.

## Discuss your medical history

Before starting treatment with Dysport, you should tell your injection specialist about all of your medical conditions, especially any that may affect your muscles and nerves.

You should also inform your specalist if you have or have had:

- Any problems with breathing, swallowing, or bleeding
- Diabetes
- A slow or irregular heartbeat or rhythm
- Any side effect or allergy to any botulinum toxin product



#### Prior treatment

Let your specialist know if you have recently received an antibiotic by injection or are currently taking any prescription or nonprescription medications, including:

Muscle relaxants

Vitamins

Sleep medicines

- Herbal supplements
- · Allergy/cold medicine

It is important to tell your specialist if you have ever received any other botulinum toxin in the past. You can still receive Dysport even if you have been treated with another toxin. Dysport was studied in adults with spasticity, including those who had:

- · Already used another botulinum toxin
- · Never used any botulinum toxin

#### IMPORTANT SAFETY INFORMATION

Most common side effects of Dysport in: (continued)

- children (2 to 17 years of age) with upper limb spasticity include: upper respiratory infection and sore throat.
- children (2 to 17 years of age) with lower limb spasticity include: upper respiratory infection, stuffy or runny nose and sore throat, cough, and fever.









#### IMPORTANT SAFETY INFORMATION

#### What is the most important safety information I should know about Dysport?

Dysport may cause serious side effects, including problems breathing or swallowing and/or spread of toxin effects, that can be life threatening and death can happen as a complication. These problems can happen within hours, or days to weeks after an injection of Dysport.

- Problems swallowing, breathing, or speaking. Treatment with Dysport can result in swallowing or breathing problems. People with pre-existing swallowing or breathing problems may be at greater risk following treatment with Dysport. Swallowing problems may last for several weeks; you may need a feeding tube to receive food or water. If swallowing problems are severe, food or liquids may go into your lungs.
- Spread of toxin effects. The effects of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism which include: loss of strength and muscle weakness all over the body, double or blurred vision, and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, and trouble breathing or swallowing. The risk of these symptoms is probably greatest in children treated for spasticity. These problems could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

Call your doctor or get medical help right away if you experience these problems after treatment with Dysport.

Do not receive a Dysport injection if: you are allergic to Dysport or any of its ingredients, or cow's milk protein; you had an allergic reaction to any other botulinum toxin product, such as Myobloc®, Botox®, or Xeomin®; or you have a skin infection at the planned injection site.

#### Before you receive a Dysport injection tell your doctor:

- About all your medical conditions, including if you have a disease that affects your
  muscles and nerves (such as ALS or Lou Gehrig's disease [amyotrophic lateral sclerosis],
  myasthenia gravis, or Lambert-Eaton syndrome). You may be at increased risk of serious
  side effects, including difficulty swallowing or breathing.
- If you have or have had any of the following: a side effect from any botulinum toxin in the past; problems with breathing such as asthma or emphysema; swallowing; bleeding; diabetes; and slow heartbeat, or problems with your heart rate or rhythm.

- If you have plans to have surgery, had surgery on your face, have weakness of your forehead muscles (trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks.
- If you are pregnant or breastfeeding or plan to become pregnant or breastfeed.

  It is not known if Dysport can harm your unborn baby or if it passes into breast milk.
- About all the medicines you take, including prescription and over-the counter
  medicines, vitamins, and herbal products. Using Dysport with certain other medicines
  may cause serious side effects. Do not start any new medicines until you have told
  your doctor that you have received Dysport in the past.

Especially tell your doctor if you have received any other injections of botulinum toxin in the last four months or ever; Myobloc®, Botox®, or Xeomin® (exactly which ones); an antibiotic recently by injection; or if you take muscle relaxants; allergy, cold or sleep medicine.

#### Most common side effects of Dysport in:

- adults with lower limb spasticity include: fall, muscle weakness, pain in your arms or legs.
- adults with upper limb spasticity include: muscle weakness.
- children (2 to 17 years of age) with upper limb spasticity include: upper respiratory infection and sore throat.
- children (2 to 17 years of age) with lower limb spasticity include: upper respiratory infection, stuffy or runny nose and sore throat, cough, and fever.
- adults with cervical dystonia include: muscle weakness, difficulty swallowing, dry mouth, injection site discomfort, tiredness, headache, muscle pain, problems speaking, injection site pain and eye problems.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Dysport. For more information, ask your doctor or pharmacist. You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.







### Insurance assistance and support

IPSEN CARES® is dedicated to helping you receive your treatment with Dysport®



#### **IPSEN CARES can help:**

- Navigate the insurance coverage process
- Provide copay assistance for eligible\* patients
- Provide free medication to financially eligible<sup>†</sup> patients through the Patient Assistance Program
- Minimize delays or interruptions in therapy





To learn more about IPSEN CARES, visit <u>IpsenCares.com/Support</u>, or call an IPSEN CARES Patient Access Specialist at 866-435-5677.

Representatives are available from 8 AM to 8 PM ET (5 AM to 5 PM PT), Monday-Friday.

For Eligibility Requirements, please see terms and conditions below, or visit <a href="mailto:lpsenCares.com">lpsenCares.com</a>.

\*Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients residing in Massachusetts, Minnesota, or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000.

Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required.

## Support when you need it

The Dysport Copay Assistance Program: Eligible\* commercially insured patients can pay as little as \$0 per prescription.

You can save up to \$5,000 if eligible for out-of-pocket expenses every calendar year.

#### Here is how the Dysport Copay Assistance Program works:

- In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000
- IPSEN CARES will process each claim and notify the patient and provider of the claim status
- IPSEN CARES will confirm every 12 months that you meet the criteria for the program.





Learn more about the Dysport Copay Assistance program at <a href="IpsenCares.com/Support">IpsenCares.com/Support</a>.

\*Patient Eligibility & Terms and Conditions (continued): Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or CoverMyMeds are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary.







## Find a Dysport® injector near you

You may already have a doctor who manages your care. However, not all doctors are trained to administer botulinum toxin, like Dysport.



If you want to add a trained Dysport injector to your care team, use our Injector Locator to find one in your area.



Scan here or visit **Dysport.com/FindInjector** 

To discover why a botulinum toxin like Dysport may be an appropriate treatment option in addition to physical or occupational therapy, talk to an injection specialist or visit **Dysport.com**.

#### IMPORTANT SAFETY INFORMATION

Most common side effects of Dysport in: (continued)

 adults with cervical dystonia include: muscle weakness, difficulty swallowing, dry mouth, injection site discomfort, tiredness, headache, muscle pain, problems speaking, injection site pain and eye problems.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Dysport. For more information, ask your doctor or pharmacist. You may report side effects to the FDA at <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.



Please see additional Important Safety Information on pages 10-11 and Full <u>Prescribing Information</u>, including Medication Guide with Important Warning.

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IPSEN CARES is a registered trademark of Ipsen S.A.. Botox, Xeomin, and Myobloc are registered trademarks of their respective owners.

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# SPASTICITY TREATMENT DISCUSSION GUIDE

## Assessing your therapy plan and how you're progressing with your goals



## What is Dysport?

DYSPORT is a prescription medicine that is injected into muscles and used to treat:

- increased muscle stiffness in patients 2 years of age and older with upper and lower limb spasticity
- · cervical dystonia (CD) in adults

#### IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about DYSPORT?

DYSPORT may cause serious side effects that can be life threatening. These problems can happen within hours, or days to weeks after an injection of DYSPORT. Call your doctor or get medical help right away if you have any of these problems after treatment with DYSPORT:

Please see full <u>Prescribing Information</u>, including <u>Medication Guide</u> with IMPORTANT WARNING. Please see additional Important Safety Information on the next page.





This guide is designed to help you assess your condition and current spasticity treatment plan to determine if you may be an appropriate patient for a botulinum toxin.

We recommend completing this questionnaire and sharing with your physical therapist (PT) or occupational therapist (OT).

Share your answers with an injection specialist at your next appointment.

1 Which of	the following syn	nptoms do you experienc	e? Check all tha	t apply.	
ADULT UPPER LIMB SPASTICITY  Muscle stiffness or tightness  Muscle spasms  Other  None		Muscle sti Muscle sp	R LIMB SPASTIC ffness or tightnes asms	SS	
2 How often	n do your sympto	ms impact your daily act	ivities?		
Rarely	Sometimes	Most of the time	All of the tin	ne	
	n during your PT	routine, or physical activi and/or OT sessions?		Helpful hint: Use	your phone to record ng the challenging you can share the video
		ny oral medications to tre			
5 Are you c	urrently receiving	g, or have you ever receive	ed, botulinum	n toxin inject	ions?
No Yes	s (which ones)		From _	(month/year)	o(month/year)

#### IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport? (continued)

• Problems swallowing, speaking, or breathing. These problems can happen within hours to weeks after an injection of DYSPORT due to weakening of associated muscles. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with DYSPORT. Swallowing problems may last for several weeks. People with certain pre-existing swallowing or breathing problems have the highest risk of getting these problems.

None	Side effects (which ones)	Other
They don't provide enough sympto They don't work long enough I sometimes forget to take them	m relief ————————————————————————————————————	
		-
7 What are you hoping to a	chieve from your treatment? Check a	all that apply.
Less stiffness or tightness Less pain	Treatment lasting longer Improved results during PT/OT sessions	Feeling like I can do more physically
8 What other goals do you	hope to achieve through treatment	?
Next store. Observed that are	J.	
Next step. Check all that app	ory.	
	is trained to administer botulinum toxin treat	

If you want to add a Dysport injector to your care team, our Injector Locator search tool can help you find one in your area.



SCAN HERE or visit Dysport.com/Injector

#### IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport? (continued)

Visit IpsenCares.com to learn about available patient support for Dysport

• Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism including loss of strength and muscle weakness all over the body, double or blurred vision, drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, and trouble breathing or swallowing.

Talk to your specialist about adding a botulinum toxin like Dysport to your treatment plan

These symptoms can happen within hours to weeks after you receive an injection of DYSPORT. These problems could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.



To discover why Dysport may be an appropriate treatment option in addition to physical or occupational therapy, talk to your doctor or visit Dysport.com/Discuss.



#### IMPORTANT SAFETY INFORMATION

#### Who should not receive DYSPORT?

Do not receive DYSPORT if you: are allergic to DYSPORT or any of its ingredients, or to cow's milk protein; had an allergic reaction to any other botulinum toxin product such as Myobloc®, Botox®, or Xeomin®; have a skin infection at the planned injection site.

#### What should I tell my doctor before receiving DYSPORT? Tell your doctor about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves, such as amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome
- have allergies to any botulinum toxin product or had any side effect from any botulinum toxin product in the past
- have or have had problems with breathing (such as asthma or emphysema), swallowing, or bleeding
- have diabetes
- have or have had a slow heartbeat, or other problem with your heart rate or rhythm
- have plans to have surgery or had surgery on your face
- have weakness in or near your muscles being treated, drooping eyelids, experienced dry eye with previous use of botulinum toxin products, or any other change in the way your face normally looks
- are pregnant (or plan to be) or breast-feeding (or planning to)

#### Tell your doctor about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal products. Using DYSPORT with certain other medicines may cause serious side effects.

Please see full <u>Prescribing Information</u>, including Medication Guide with IMPORTANT WARNING.

Do not start any new medicines until you have told your doctor that you have received DYSPORT in the past. Especially tell your doctor if you: have received any other botulinum toxin product in the last four months or any time in the past (be sure your doctor knows exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants, an allergy or cold medicine, or a sleep medicine.

#### What are the possible side effects of DYSPORT?

- The most common side effects in adults with upper limb spasticity include muscle weakness; in adults with lower limb spasticity include muscle weakness, pain in arms or legs, and falls
- The most common side effects in children (2 to 17
  years of age) with upper limb spasticity include upper
  respiratory tract infection and sore throat; in children
  with lower limb spasticity include stuffy or runny nose,
  sore throat, cough, and fever
- The most common side effects in people with cervical dystonia include muscle weakness, muscle pain, difficulty swallowing, dry mouth, problems speaking, injection site pain or discomfort, feeling of tiredness, eye problems, and headache

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DYSPORT. For more information, ask your doctor or pharmacist. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.





## SPASTICITY CARE EXTENSION FORM



Directed to:	Phone:	Date:		
Patient:				
, , , , <u></u>				
Scre	eening Checklist			
What type of OT Start date:	Location:	How often:		
rehab does the patient receive? PT Start date:	Location:	How often:		
Is the patient currently receiving, or have they ever	received, botulinum toxin treatment	t?		
NO YES Date of last injection:	Treating physicia	n:		
Medication:	Total dose:			
Treatment goals:				
Current medications for managing spasticity:				
Current issues:				
	-	_ Spasticity location:  (print the form and circle location or mark with an x)		
Please send all injection notes to the referring ph or occupational therapist listed below:  To:	ysical ( )			
Fax/Email:		\		

 ${\tt OT=} occupational\ the rapy; {\tt PT=} physical\ the rapy.$ 

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Phone: \_\_\_